July 13, 2026

Office of Management and Budget
Office of Federal Financial Management

Submitted electronically via Regulations.gov

Re: Comment on the Proposed Rule, *Regulation for Federal Financial Assistance*, 2 CFR Part 200, 91 Fed. Reg. 32198 (May 29, 2026) (Docket No. OMB-2026-0034)

Dear Office of Management and Budget:

The Association for the Accreditation of Human Research Protection Programs (AAHRPP), National Advisory Committee on Human Research Protections (NACHRP), and Public Responsibility in Medicine and Research (PRIM&R) respectfully submit this joint comment on the proposed *Regulation for Federal Financial Assistance*. We represent Human Research Protection Programs (HRPPs), professionals dedicated to protecting participants in research, and Institutional Review Boards (IRBs).

As drafted, several provisions of the proposed rule do not account for the legal and ethical obligations owed to research participants under the Common Rule (45 CFR part 46), FDA regulations (21 CFR parts 50 and 56), and the Belmont Report. The new rule would significantly alter current practices, which would create unintended negative consequences for research participants and reduce public trust in science. For these reasons we ask that the final rule not adopt proposed changes that would: (1) subordinate scientific and peer review to the discretion of a senior appointee or designee; or (2) alter the process for suspending and terminating projects in a way that permits the abrupt termination of awards without a transition period sufficient to protect enrolled participants.

These concerns arise at two points in the award life cycle, and the comments below address each in turn.

Comment 1. Scientific Merit Review as a Precondition for Ethical Human Subjects Research [§ 200.205]

Proposed Provision. Proposed § 200.205 establishes a new, pre-issuance review of every discretionary award by a senior appointee, who must find, among other things, that the award "demonstrably advance[s] the President's policy priorities, and the national interest...." The provision states scientific peer-review recommendations "remain advisory" and may not be "ministerially ratified" or "routinely deferred to the recommendations of others, but must instead use their independent judgement when evaluating Federal award proposals." This language allows a senior appointee (or their designee) to override the scientific or peer-review determination of merit. Source: https://www.govinfo.gov/content/pkg/FR-2026-05-29/pdf/2026-10817.pdf at p. 32248-49.

Concern. This language separates the funding decision from the scientific merit determination in a way that is not merely administrative. It removes an ethical requirement of human subjects research: minimizing possible harms to participants. Under the Belmont Report's principle of "Beneficence" and Common Rule requirements, risks to research participants are justified only when they are reasonable in relation to the importance of the knowledge the study is expected to produce. The Common Rule codifies this at 45 CFR 46.111(a)(2) (and FDA at 21 CFR 56.111). Peer review by the funding agency provides an essential mechanism through which scientific merit is established. IRBs assess the ethics of a study but rely on the funding agency's expert scientific review for rigorous merit evaluation. A provision that allows a non-scientist appointee to override or disregard peer review severely weakens this critical element of participant protection.

Practical Impact. Scientific peer review and IRB review serve different, but complementary critical purposes. Peer review on behalf of the funding agency evaluates scientific merit, including whether a study is rigorous and likely to yield meaningful results, while IRBs primarily evaluate whether the risks to participants are ethically justified. IRBs are not resourced to serve as the primary adjudicator of scientific merit and rely on peer review assessments as part of their determinations as to whether the research risks are minimized and reasonable in relation to the benefits of the research. If a non-scientist appointee can override or disregard peer review, that foundation is no longer assured; the burden then shifts to IRBs and institutions. To address this, institutions would need to build new scientific review infrastructure, which would impose a significant burden on institutions and potentially lead to delays in scientific advances. Further, such review mechanisms would duplicate a function the funding agency is far better equipped to perform.

Recommendation. Scientific and peer review should remain the basis for scientific merit determinations by funding agencies and should not be just advisory. Further, the senior appointee's discretion should not extend to funding human subjects research (or any other research) that expert review has found to be scientifically unsound. At a minimum, we therefore recommend adding to § 200.205 language such as the following: *For awards supporting research involving human participants, a favorable scientific or peer review determination of scientific merit shall be a necessary condition for issuance of the award.*

A senior appointee or designee may not issue such an award over a scientific or peer-review determination that the research lacks scientific merit.

Comment 2. Discretionary Termination Must Provide Notice and an Orderly Participant Protection Transition [§§ 200.340, 200.341, 200.342]

Proposed Provision. Proposed § 200.340 authorizes an agency to terminate an award, in whole or in part, if the Federal agency determines that the award "does not effectuate program goals, Federal agency priorities, or the national interest as they exist at the time of the termination." Proposed § 200.341 requires only a brief written notice, states the agency "is not required to provide a detailed or exhaustive analysis," and provides the stated reasons "may apply to an individual award or class of awards." Proposed § 200.342 would preserve objection, hearing, and appeal rights only for terminations based on noncompliance, not for discretionary, priority-based terminations. These provisions set no minimum notice period and no delayed effective date. Source: https://www.govinfo.gov/content/pkg/FR-2026-05-29/pdf/2026-10817.pdf at p. 32258 – 60.

Concern. This comment concerns timing, specifically how quickly a termination takes effect. Applicable human subjects ethical and regulatory requirements create obligations that do not end the moment funding does. When an award is terminated during a study and the termination is effective immediately, participants may still require safety monitoring, scheduled follow-up, management of adverse events, communication of new findings that bear on their health, or safe discontinuation of an investigational agent. Because the proposed rule permits abrupt, minimally explained, and potentially broad terminations across an entire group of awards with no appeal and no defined transition period, an award's funding can end before these time-sensitive participant protection steps can be carried out. There are risks in general to the premature termination of research, but particularly so when terminations are unexpected or sudden. Further, abrupt terminations without an orderly withdrawal plan can increase participant risk, undermining trust in the research process.

Termination also does not change or eliminate the funding recipient's separate obligations under applicable regulations, which continue independent of funding. The IRB must maintain oversight of the study, and investigators must continue to protect enrolled participants, monitor and report adverse events and unanticipated problems, and comply with the IRB's determinations. The result of immediate termination of funding creates a direct conflict: The funding is terminated while other Federal requirements continue to mandate both IRB oversight and investigator compliance.

Practical Impact. Consider a multi-site clinical trial in which participants have received an investigational product that requires tapered discontinuation and post-exposure safety monitoring. If the sponsoring agency issues a termination across a group of awards effective immediately, funding for study visits, laboratory monitoring, and drug safety oversight would cease before participants can be transitioned off the intervention safely. A termination framework designed around financial considerations applied without a

transition period to human subjects research, turns an administrative decision into a direct and immediate risk to participant safety. The impact is not limited to safety. Applicable human subjects regulations also require an orderly transition and a proper study closure. Consequently, an immediate termination of Federal funds leaves the institution to either fund that transition from its own resources or carry it out improperly, in violation of those requirements. Additionally, out of an abundance of caution, institutions may avoid developing or participating in research that may pose ethical concerns or incur significant costs to the institution should a Federal award be terminated, potentially decreasing the range of options available for patients with debilitating or life-threatening conditions and slowing important scientific advances .

Recommendation. The final rule should require advance notice and a minimum transition period before a discretionary termination of a human subjects award takes effect. Further, the final rule should limit the situations under which discretionary termination may occur. We recommend adding to § 200.340 (or § 200.341) language such as the following: *For awards supporting research involving human participants, a discretionary termination under this section shall not take effect until the recipient has received advance written notice and a reasonable transition period sufficient to protect participant safety, including required follow-up and monitoring and the safe discontinuation of interventions (the duration of which could vary on a case-by-case basis). This section does not limit an agency's authority to suspend or terminate an award for cause.*

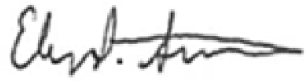
General Comment. While our comments focus on ensuring protections of research participants are not weakened by the proposed rule, we also would like to note several of the provisions contravene a recent plan released by the U.S. Department of Health and Human Services (HHS). The plan, "Operation Trialblazer: HHS Roadmap to Maintaining U.S. Leadership in Early Clinical Research and Development," seeks to "modernize and accelerate stages of medical product development" by identifying and removing "unnecessary burden from the path between a promising scientific discovery and the patients who need it, without compromising the privacy, safety or ethical standards."

To achieve these goals, the Federal government must better support the pipeline for scientific discovery by undergirding precedent research (e.g., preclinical work in animals, basic research, and investigator-initiated clinical research), continue to create conditions that develop and train scientists and research staff, ensure funding for robust research that advances scientific knowledge, facilitate collaborations between U.S. researchers and international colleagues to leverage the global body of knowledge and speed discoveries, and disseminate research findings through conferences, papers, and other forums.

Scientific discovery, including a robust clinical trials pipeline, has been a powerful economic engine for the U.S. for decades. In addition to weakening protections for research participants, the proposed OMB rule would increase burden on research organizations and divert efforts away from activities that fuel scientific discovery. Collectively, these changes would undermine the U.S. position as a global leader in research.

We appreciate the opportunity to comment and welcome the chance to provide additional information or to assist OMB with implementing language.

Respectfully submitted,



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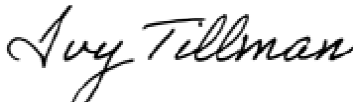

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