August 24, 2026

Suzanne H. Plimpton, Reports Clearance Officer
National Science Foundation
Randolph Building, 401 Delany Street
Alexandria, Virginia 22314

Submitted electronically via Regulations.gov

Re: Agency Information Collection Activities; Proposals, Submissions, and Approvals: National Science Foundation Proposal/Award Information Guidance on Financial Assistance (June 24, 2026) (Docket Number: NSF-2026-OTR-0001)

Dear Ms. Plimpton:

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 revisions to the *National Science Foundation Proposal/Award Information Guidance on Financial Assistance*. We represent Human Research Protection Programs (HRPPs), professionals dedicated to protecting participants in research, and Institutional Review Boards (IRBs).

Most responses submitted during the comment period for the Proposed Rule, *Regulation for Federal Financial Assistance*, 2 CFR Part 200, 91 Fed. Reg. 32198 (May 29, 2026) (Docket No. OMB-2026-0034) opposed the rule as written. Further, the U.S. Senate passed a bipartisan continuing resolution on August 8 blocking implementation of the proposed rule. These actions demonstrate that considerable opposition to the OMB proposal exists. Consequently, we urge the National Science Foundation (NSF) to halt or significantly revise implementation of its proposed guidance, which includes alignment with a proposed OMB rule that may be stopped permanently or substantially altered before it goes into effect.

The comments we provide mirror those previously submitted for the Proposed Rule, *Regulation for Federal Financial Assistance*, 2 CFR Part 200, 91 Fed. Reg. 32198 (May 29, 2026) (Docket No. OMB-2026-0034). As drafted, several provisions of the NSF Guidance on Financial Assistance (GFA) 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 guidance 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 NSF not adopt proposed changes that would: (1) subordinate scientific and peer review to the discretion of a senior appointee or designee; or (2) disrupt the pipeline critical to advancing science.

Comment 1. Draft GFA Guides 8, Proposal Processing and Merit Review, and 9, Proposal Withdrawals and Declinations

Proposed Change. GFA Guides 8 and 9 closely align with proposed § 200.205. This proposed OMB provision 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 OMB 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.

Concern. This language in the proposed OMB rule 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. We urge the NSF to ensure scientific and peer review 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.

Comment 2. Overall Impact on Science

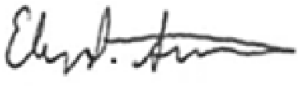
We note that several of the proposed revisions contravene a recent plan released by the U.S. Department of Health and Human Services (HHS). The plan, "Operation Trialblazer: HHS Roadmap to Maintaining U.S. Leadership in Early Clinical Research and Development," seeks to "modernize and accelerate stages 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."

NSF plays a key role in supporting scientific discovery that supports the goals described in Operation Trialblazer, because its funding undergirds precedent research (e.g., preclinical work in animals, basic research, and investigator-initiated clinical research), creates conditions that develop and train scientists and research staff, facilitates collaborations between U.S. researchers and international colleagues to leverage the global body of knowledge and speed discoveries, and supports disseminating 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 revisions to NSF guidance, like 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 to the NSF.

Respectfully submitted,



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