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December 4, 2023

Office of Federal Financial Management
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Proposed Rule: Guidance for Grants and Agreements (88 FR 69390)

Submitted via Regulations.gov.

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the Office of Management and Budget (OMB) on proposed revisions to the OMB Uniform Guidance.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

The AAMC appreciates the substantial work that OMB has taken on in order to regularly review the Uniform Guidance and make efforts to streamline and update the guidance as needed such that it is maximally clear and effective, and minimally burdensome, to the federal grantee community. We agree with the detailed analysis by our colleagues at the Council on Governmental Relations (COGR)¹ on the proposed revisions and support COGR's recommendations with regard to the proposed rule. We also commend to OMB the work of the Association of Research Libraries regarding the expanding role of the library and proposed changes to 2 CFR 200 Appendix III.B.²

¹ https://www.cogr.edu/sites/default/files/COGR_Response_FRN%2088%20FR%2069390_DEC4.pdf

² <https://www.arl.org/wp-content/uploads/2023/08/2023-08-09-ARL-OMB-Letter.pdf>

In this letter, we highlight several of those recommendations regarding changes to 2 CFR part 200 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards), which have particular importance to AAMC's member institutions.

[200.414- Indirect Costs]

Indirect costs, or Facilities and Administrative (F&A) costs, are an ineluctable expense incurred by institutions as a part of carrying out the work of federal research grants and are inseparable from the research itself. F&A reimbursements to institutions are an essential part of supporting the infrastructure costs needed to conduct research. We appreciate that OMB has incorporated stronger language around acceptance of negotiated F&A cost rates by federal agencies (§ 200.414(c)(2)) and additionally echo COGR's call for a timelier process should new cost rates need to be established.

AAMC appreciates OMB's proposal to increase the *de minimis* F&A rate from 10 to 15 percent, while noting that this is still below what would be considered a fair rate. Appendix III, section C.9.a, references a default allowance of "24% of modified total direct costs" to recover administrative costs, and we support the recommendation to update § 200.414(f) to state that "Recipients and subrecipients that do not have a current Federal negotiated indirect cost rate (including provisional) rate may elect to charge a *de minimis* rate of up to 24 percent of modified total direct costs (MTDC)."

[200.315- Intangible Property]

§ 200.315(a) of the proposed rule would provide that:

Title to intangible property acquired under a Federal award vest upon acquisition in the recipient or subrecipient. The recipient or subrecipient must use that intangible property for the originally authorized purpose and must not encumber the property without the approval of the Federal agency or pass-through entity.

This proposed language of § 200.315 would contradict the Bayh-Dole Act (PL 96-517) and its implementing regulations at 37 CFR. The Act specifically defers to research institutions to take title to patents arising from federally funded research, and to license or disperse accordingly to promote the commercialization and application of such inventions. Section .315(c) does provide that:

The recipient or subrecipient is subject to applicable regulations governing patents and inventions, including government-wide regulations in 37 CFR 401.

However, that language fails to clarify or address the concern, for example, whether licensing arrangements would require agency approval. We urge that the original text of 2 CFR 200 be restored.

[200.201 Use of Grants, Cooperative Agreements, Fixed Amount Awards, and Contracts]

The AAMC strongly supports COGR's recommendation that paragraph 200.201(a) include a statement recognizing agreements under Other Transaction Authority (OTA) as an available type of legal instrument not covered by § 200 (i.e., not a grant, contract, or cooperative agreement), but to clarify that, "OTA instruments should only be used when grant, cooperative agreement, or contract vehicles are not suitable."

OTAs are often intended to expedite agreements between federal agencies and recipients, but they can lead to protracted negotiations and their increasingly widespread use has led to inconsistent practices. AAMC further supports the recommendation that OMB work with federal agencies to develop suitable standards for the use of OTA agreements.

AAMC would be glad to provide any additional comments on the proposed revisions to OMB as the rulemaking process moves forward. Please feel free to contact me or my colleagues Anurupa Dev, PhD, Director of Science Policy and Strategy (adev@aamc.org) and Stephen Heinig, Director of Science Policy (sheinig@aamc.org), with any questions about these comments.

Sincerely,



Heather H. Pierce, JD, MPH
Acting Chief Scientific Officer
Senior Director for Science Policy and Regulatory Counsel

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer