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Russell Vought
Director
Office of Management and Budget
Executive Office of the President
725 17th Street NW
Washington, DC 20503

RE: Regulation for Federal Financial Assistance

Submitted electronically at www.regulations.gov.

Dear Director Vought:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the proposed Regulation for Federal Financial Assistance. The proposed changes to federal grantmaking have far-reaching implications for infectious diseases (ID) research, public health and access to care for vulnerable populations.

Infectious diseases clinicians and public health practitioners depend on support from the federal government to research the most effective treatments for their patients and provide services that protect the public. These comments focus on impacts to agencies like the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and others in the Department of Health and Human Services; however, the impact of this regulation will not be limited to those agencies because this proposal is so broad. There are health-related grants in other departments, including the Departments of State and Agriculture, that will be impacted by this rule. IDSA believes that the proposed regulation will precipitously slow or potentially halt the prevention, treatment and investigation of infectious diseases and discovery and implementation of 21st century innovations and cures. **IDSA believes that the proposed regulation changes the federal funding landscape in ways that will impede science and threaten the health of Americans.**

IDSA opposes the transfer of authority over federal grantmaking from federal agencies staffed by subject matter experts to the Office of Management and Budget (OMB). As written, the regulation allows the executive branch to overrule decisions made by Congress about how federal funding should be spent. While the proposed rule purports that "the proposed revision is not unduly coercive," the ability to drastically change course with each new presidential Administration would lead to a lack of continuity and is detrimental to the pursuit of scientific discovery and consistency for grantees. **We call on OMB to rescind this rule.**

Parameters for funding are unclear

Risk posed by applicants [§200.206]: The proposal includes several terms that will serve as metrics for allowable funding which are undefined, leaving considerable uncertainty for grantees. The proposal seeks to bar funding from applicants with a "history of questionable practices" but does not define this term, which does not provide enough clarity to applicants in what activities are allowable. This leaves a wide breadth of ambiguity, which may also allow arbitrary barring of applicants based on the interpretation of "history of questionable practices." **IDSA calls on OMB to define "questionable practices" and explicitly explain how the definition was determined if this rule is finalized.**

Merit of proposals [§200.205]: Additionally, the proposal does not allow funding of "initiatives that compromise public safety or promote anti-American values," but these terms are not defined.

The proposed regulation seeks to "institutionalize needed reforms in the Federal grantmaking process" but goes beyond that to allow OMB to supersede the priorities and action plans of individual departments and agencies. Grantees are also given no ability to appeal decisions. **IDSA calls on OMB to define "anti-American values" and what types of funding would compromise public safety if this rule is finalized.**

The proposed rule seeks to improve transparency, accountability and oversight for use of federal taxpayer dollars. Contrary to this goal, parts of the proposed rule will slow down achieving the goals of federal grants and, in some cases, increase waste of taxpayer dollars as research or public health programs are stopped and started according to political priorities. As detailed below, adding a layer of review by political appointees for every grant will delay the process of finding new discoveries that benefit Americans.

Instability in funding will limit federal research capacity

Despite this Administration stating the importance of building the pipeline of researchers to bolster this country's research capacity, this proposed regulation would undermine that development and weaken the U.S.'s research and medical workforce. Nationally, across all physician specialties in the United States, the Health Resources and Services Administration (HRSA) estimates there will be a shortage of more than 141,000 full-time equivalent physicians by 2038. Medical specialties like infectious diseases are already facing country-wide workforce shortages that will be exacerbated by instability in grant funding; studies show that roughly 80% of U.S. counties do not have a single ID physician that can treat patients, and over 50% of ID training programs now go unfilled, further contracting the pipeline.

Many ID physicians also engage in clinical research as physician-scientists. The physician-scientist workforce is incredibly important to advancing clinical research, improving patient outcomes, and developing novel vaccines and medical countermeasures. However, it continues to be extremely difficult for many early-career ID researchers and physician-scientists to receive the funding needed to enter and remain in the workforce. Further instability around the grant review and issuance process, and the lack of predictable, consistent funding, will contribute to a further decline in the workforce for specialty care and ID research. Without sustainable grant funding, researchers will be reliant on more clinical time to fund their salaries and will have less time to devote to research.

ID clinical and research training and early-career development are almost entirely driven by federally funded grants, usually through agencies like NIH and the National Institute for Allergies and Infectious Diseases (NIAID). Key federally funded programs that support early-career training and research include:

- Physician-Scientist Pathway to Independence Award – NIAID/NIH
- T32 Research Training Grants – NIAID/NIH
- R25 Education Projects – NIAID/NIH
- R38 Stimulating Access to Research in Residency (StARR) in combination with K38 Career Development – NIAID/NIH
- Faculty Early-Career Development Program (CAREER) – National Science Foundation
- Early-Concept Grants for Exploratory Research (EAGER) – National Science Foundation

If federally funded opportunities are seen as cancellable at any point in the early-career process based on the proposed regulation's language, this will dissuade students from pursuing critical careers in ID research, and biomedical and clinical research overall. Students will likely seek funding from other sources, and from institutions outside the U.S., which will deplete our research workforce. Without a strong pipeline into the research workforce for early-career researchers and students, we will lose our capability to innovate across the ID spectrum, including developing new antimicrobials, medical countermeasures, vaccines and diagnostic assays. This will be especially detrimental in public health emergencies involving infectious diseases threats when research must scale up rapidly to respond. **We request that OMB clarify how it will prevent losses to the pipeline of future researchers if this rule is finalized.**

Review process [§200.205]: We believe the proposed regulation would detrimentally impact research funding and could be used to arbitrarily cut critical federal research, without recourse for grantees. The proposed regulation expands the role of political prioritization in research funding and scientific grantmaking. In theory, research priorities could change every four years under new Administrations based on their political priorities, which would dramatically curtail scientific progress. Many federal grants are awarded for longer than four years. In many instances, this would not provide sufficient time to establish laboratories, hire staff and complete studies. The process of research is not linear and can be unpredictable, not adhering to a particular timetable. Research funding must be evaluated and ensured by scientific experts who have clear understandings of the need for continuity in research funding and the research process.

The proposed regulation adds layers of unnecessary regulatory review into the grant process that will ultimately slow down grant issuance and dispersal. Specifically, the proposed regulation includes a pre-issuance review "to ensure that Federal award proposals selected for funding are consistent with applicable law, Federal agency priorities, and national interest." The issuance of grants is already an incredibly lengthy process subject to immense oversight; this will only make that process longer without adding additional scientific oversight. We disagree with the review process outlined, which makes political review formal and required for grant issuance, and limits the role of peer review recommendations by experts in the overall process.

Peer review process for grants [§200.205]: The proposed regulation will make federally funded science incredibly susceptible to politicization due to its undermining of strong peer review processes. The requirement to base funding decisions on "gold standard science," a term that is not defined in the proposal, creates significant uncertainty and ambiguity. While we recognize the Executive Order (EO)14303 and its subsequent implementation memo included some overarching goals, we are not aware of any rulemaking with notice and comment to define this term and solicit feedback from the public. Despite the goal of "gold standard science" being outlined as "subject to unbiased peer review," the proposed regulation does not support this, and leaves research susceptible to biased, politicized influences. If gold standard science means subject to unbiased review, then gold standard science should also be subject to unbiased funding decisions. Grantees should not be penalized for not implementing an unclear definition of research that has been public for roughly one year. Research is a decades-long process in many cases, and must be reliant on clear, evidence-based peer review processes and definitions that do not change with each Administration. **At a minimum, we call upon OMB to provide a clear definition of "gold standard science" and metrics that will be used to evaluate grant applications.**

Prohibition of using federal funds for covered foreign collaborations [§200.220]: Global cooperation is critical to research, and especially to the study of infectious diseases as well as the prevention, preparedness and responses to outbreaks and pandemics. Many serious infectious diseases originate outside of the U.S. and studying them before they reach the U.S. is critical to ensure that vaccines, diagnostics and treatments are available when Americans ultimately need them. Conducting research outside of the U.S. can also be an effective strategy to reduce the costs of research that benefits Americans. We are concerned that the proposed regulation will limit the ability of researchers to work with international collaborators. While a federal agency may authorize an exception to this section if the activity does not pose a risk to national security and is in the national interest of the United States, these terms are not clearly defined. This could result in reluctance of international partners to collaborate with domestic researchers and make American scientific collaborators less competitive compared to European and other international partners. The regulation will have a chilling effect as U.S. researchers refrain from international collaborations that could benefit Americans because of their fear of being targeted for additional grant requirements and scrutiny or denied funding altogether.

Limiting U.S. researchers' ability to form international partnerships for ID research will weaken our readiness for future public health emergencies, impede scientific advances, reduce our nation's global standing and restrict Americans' access to scientific discoveries.

Limitations on public health funding will hinder pandemic preparedness

We are incredibly concerned that the proposed regulation will detrimentally impact public health preparedness to respond to infectious diseases at the federal, state and local level. This will put the country at risk of both naturally occurring and bioterrorism-related public health threats. Currently, public health department funding is dependent on federal grants, predominantly from the CDC; 75% of CDC funding goes directly to state and local governments and organizations that protect people in communities across the country. Critical federal grant funding through CDC supporting health departments, which would be at great risk under this rule, includes:

- **Antibiotic Resistance Solutions Initiative** – Invests in national infrastructure to detect, respond, contain and prevent resistant infections across health care settings, communities, the food supply and the environment (e.g., water, soil).
- **Advanced Molecular Detection** – Integrates the latest next-generation sequencing technologies with bioinformatics and epidemiology expertise across CDC and the nation to help us find, track and stop disease-causing pathogens faster than ever before. This funding directly supports biosurveillance at public health departments across the country.
- **Public health data modernization efforts** – An almost decade-long effort to move public health from tracking threats to predicting them through updating and improving surveillance systems across the country. Funding supports health care, academic, public health and research partners.

- **The Epidemiology and Laboratory Capacity (ELC) Program** – Invests in health departments to support epidemiology, laboratory and health information systems and help build a skilled, response-ready workforce. ELC serves as a rapid and reliable funding mechanism during infectious diseases outbreaks and public health emergencies.
- **Public Health Emergency Preparedness (PHEP) Program** – The PHEP cooperative agreement has aided public health departments across the nation since 2002. This helps health departments strengthen their abilities to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear and radiological events.
- **317 Immunization Program** – The 317 program supports efforts at the state level to ensure that communities have access to protection against vaccine-preventable diseases.

These grant programs constitute critical sources of funding to address public health priorities across the country, and rely on consistent, guaranteed funding to support workforce and capacity. Recent examples of actions by HHS Secretary Robert F. Kennedy Jr. exemplify the impact of termination of certain programs without requisite evidence-based reasoning, such as freezing and cutting NIH grants without justification, and recent cuts to the $500 million in grant funding for mRNA vaccines, despite their clear use in preparing for future pandemics and infectious diseases threats. Federally funded grants and programs should not be able to be terminated due to apparent politicization of policies and priorities.

Termination and suspension [§200.340]: The proposed regulation is potentially detrimental to responses to public health emergencies. A lack of reliable funding, or funding with the threat of termination without warning, directly undermines public health readiness. Public health emergencies occur quickly, and funding mechanisms must be guaranteed to be in place before a federal response occurs. State and local public health staff and technology must also be in place before an emergency occurs in order to respond rapidly. If the ability to use grant funding to prepare for and respond to threats is impeded by a lack of federal support, we put American lives at risk in the event of public health emergencies.

Further, agencies' existing authority to terminate discretionary awards when the award "no longer advances agency priorities" would be clarified to mean the federal agency's priorities, not the priorities of a state or local pass-through agency. The rule will also allow for discretionary termination if the award no longer advances the "national interest" and allow agencies to add other reasons for discretionary termination "as appropriate." States and localities have vastly different public health needs (e.g., tick-borne illness like Lyme disease and alpha-gal syndrome in rural communities, avian influenza circulation in areas with large-scale livestock production, emerging and re-emerging mosquito-borne diseases in parts of the country with increasing heat and heavy rainfall). Readiness and response priorities must be allowed to be considered locally without the possibility of funding being cut with no warning. **We ask OMB to clarify how the federal government will continue to meet local and state public health needs if this rule is finalized.**

Reduction in access to care, especially for vulnerable populations

Statutory and national policy requirements [§200.300]: Prohibitions on the use of grant funding for diversity, equity and inclusion and what are characterized as "gender ideology" activities in the proposed regulation will limit services for patients with HIV/AIDS. The Ryan White HIV/AIDS Program and other grants from the Bureau of Primary Health Care provide lawful services to patients highly vulnerable to HIV who often do not have other sources of care. Reducing services for these populations can have serious, detrimental impacts on their health. Without prevention and treatment services for HIV, communities across the nation will be at higher risk from this life-threatening infectious disease, thereby increasing human and health care costs.

When a patient with an infectious disease is unable to access care, not only is that patient negatively impacted, but they are also at greater risk of spreading their untreated infection to others. Restricting access to care can lead to outbreaks and negatively impact the public health of an entire community. **IDSA calls on OMB to provide details about how the federal government will ensure that no individual loses access to health care because of this regulation.**

Front-line health care providers are needed, especially in rural communities, to treat patients with infectious diseases and detect outbreaks. These safety net providers, including Ryan White HIV clinics, community health centers and rural health clinics will potentially have their funding threatened. The health of residents in communities across the nation will be harmed as clinicians are subject to restrictions on the populations they can serve and the services they can provide. In

addition to providing health care to patients with chronic infections like HIV, ID specialists are involved in all aspects of health care (e.g., transplants, cancer treatment, common surgeries like knee or hip replacement).

Additionally, ID clinicians are needed to combat the growing threat of antimicrobial resistance (AMR). Slowing down infection prevention and treatment will allow AMR to increase in prevalence and severity, threatening the ability of the health care system to provide needed surgeries and treatments for cancer. AMR can make diseases that are currently treatable no longer susceptible to available antibiotics. The proposed rule threatens access to ID specialty care that is needed to keep our health care system functioning and keep people healthy, so they do not spread disease to others.

Funding in the Ryan White HIV/AIDS Program Parts A & B is provided through formula grants that go to cities and states, respectively. Due to statutory requirements, we believe this funding is not subject to termination without notification under the proposed rule. However, Parts C, D and F would be subject to termination, cutting off funding without warning to community-based organizations supporting people with HIV. Additionally, AIDS Education Training Centers that provide technical assistance to clinicians providing services to people living with HIV are threatened, as well as Part F, which provides oral health care, a vast unmet need for this population.

Impact on scientific collaboration and communication

The proposed regulation poses an extreme assault on the ability of federally funded researchers to collaborate with peers and learn from others in the field. Science is an inherently collaborative field. Scientific research and inquiry rely on collaboration across institutions, fields and specialties through attending scientific conferences, publication of research and continuous scientific discourse – this leads to scientific discoveries supported by work that could not have been achieved by one researcher. Collaborative effort also ensures consistent communication between researchers, clinicians and patients, which helps ensure that research questions are focused on patient needs and that research findings more rapidly reach the bedside and improve patient outcomes.

Conference attendance [§200.432]: The proposed rule would disallow costs for participation in conferences without express agency approval and inclusion of the conference in the award terms. Approval would be restricted to conferences that serve to advance program outcomes or the general administration of grants. Under current rules, conference attendance related to the scientific work of a grant is a standard, routine allowable cost that allows the grantee to share their work with others in the field that may benefit from learning about it and/or replicate this work to benefit residents of their community. Arbitrary denial of the ability to attend conferences and learn from peer scientists and clinicians in the field will hurt the progress of science and development of new treatments and advances in public health. The education, scientific discourse and collaborative work that occur at conferences are fundamental to the research process and will ultimately hinder scientists' ability to develop their work.

Publication and printing costs [§200.461]: The stipulation around journal publication in the proposed regulation also limits researchers' abilities to collaborate. IDSA understands and shares the commitment to responsible publication of federally funded scientific research. However, the rule would make publication costs unallowable unless such costs are expressly required by statute or approved in advance by the federal agency on a case-by-case basis and included in the terms of the award.

Preserving the strength of scientific journals is fundamental to improving human health. Federally funded research that has gone through peer review and been published in journals is critical to inform medical practice, improve patient outcomes and save lives. Often research in one area of medicine provides breakthroughs that can be repurposed in other areas. The examples below demonstrate the critical importance of maintaining NIH support for peer-reviewed scientific publication:

- **Dorman, Susan E., Nahid, Payam, et al. (2021), "Four-Month Rifapentine Regimens With or Without Moxifloxacin for Tuberculosis," *New England Journal of Medicine.*** This article showed that the efficacy of a four-month rifapentine-based regimen containing moxifloxacin was noninferior to the standard six-month regimen in the treatment of tuberculosis. The research published here helped shorten treatment times for TB, improving patients' lives and reducing health care costs. **Funded by CDC.**
- **Cohen, Myron S., Chen, Ying Q., et al. (2011), "Prevention of HIV-1 Infection With Early Antiretroviral Therapy," *New England Journal of Medicine*.** This article demonstrated the effectiveness of antiretroviral therapy that reduces viral replication could limit the transmission of human immunodeficiency virus type 1 (HIV-1) in serodiscordant couples. This publication led to tremendous gains in preventing HIV transmission and helped launch the Undetectable = Untransmittable campaign. **Funded by NIH.**

- **Garcia, J., Daniels, J., Lee, Y., et al. (2024), Naturally occurring T cell mutations enhance engineered T cell therapies, *Nature*.** This publication demonstrated the effectiveness of inserting a gene mutation found in certain lymphomas, called CARD11–PIK3R3, into therapeutic T cells. The mutation makes the T cells more efficient at treating solid tumors — without turning those cells cancerous. **Funded by NIH.**

These articles are a small sampling of the many published pieces funded by federal grants that have improved patient care and saved lives. Publication in journals remains one of the primary ways that advancement of new scientific knowledge is communicated to the field and the public. Limiting publication limits the accessibility of research, which contradicts the goal of transparency of federally funded research. We also believe that the proposed limitations on publication would limit the options for peer review on federally funded scientific publications, which would limit the overall reproducibility of research.

Memberships, subscriptions and professional activity costs [§200.454]: The proposed rule also proposes that grant funding may be used on a recipient's or subrecipient's membership in professional and technical organizations only if necessary to fulfill the award requirements and requires prior written approval of the federal agency. Membership organizations allow collaboration with peers, which is key to disseminating learning and building the pipeline of early-career clinicians and scientists.

Advertising and public relations [§200.421]: Further, the proposed regulation's ban on public communications (which would include educating the public about research findings) further contradicts the goal of transparent science and research. The proposed regulation states, "American taxpayers have a right to know the projects that their tax dollars are supporting and the entities to which those dollars are flowing," but without public communications, taxpayers will not have access to this information. Communications with the public about how to stay safe and healthy empower communities, families and individuals to make informed health decisions.

The ongoing FIFA World Cup 2026 taking place throughout North America highlights the need for public communication across federal, state and local public health workforces supported through federal grants and funding, as public health authorities in cities hosting games have collaborated with infectious diseases clinicians to educate people attending games about how to protect themselves from health threats like respiratory viruses, insect-borne diseases, foodborne illnesses and extreme heat. Any limitations on public communication will hamper future efforts to conduct public health outreach, limiting responses and education in other large public gatherings.

We also believe that, in line with our comments above, if researchers see federal grants as limiting their abilities to communicate science and progress their work, they will seek funding opportunities outside the United States, depleting our workforce and leaving us without strong clinical research capacity.

IDSA highlights the following changes in the proposed rule that could help streamline funding:

Unified federal grant platform [§200.202]: We believe that the requirement that all funding opportunities be posted on grants.gov, creating a single platform, will help streamline the federal grant process. The current process requires looking across multiple federal agency grant sites to find applicable grants, which requires excess time and work researchers need to devote.

Streamlining of language [§200.204]: Additionally, the requirement that notice of funding opportunities be written in plain language and should not require applicants to employ technical or legal consultants would ensure a streamlined grant application process. Many institutes and researchers do not have access to full-time technical and legal consultants, and even for those who do, this stipulation adds a layer of administrative work that is unnecessary for the grant process.

High-volume grant application changes [§200.204]: We also support measures to help agencies determine the best candidates for grants, such as the proposal to add statements of interest (SOI) as part of notices of funding opportunity when high application volume or lengthy proposals are expected. We agree that this would help eliminate the burden of work on applicants by avoiding excess work on full proposals at an early stage. We further support the language that ensures these SOIs are not compared against full applicant proposals, considering the difference in overall work and requisite requirements.

Respect of funding with federal statute [§200.340]: IDSA also agrees with the proposed rule's exception for awards granted through federal statutes. Essential medical programs and public health programs that have entitlement under federal statute, such as Ryan White Parts A and B, Medicare and Medicaid, should continue to be excluded from this regulation.

Multi-year grants [§200.202]: Forward funding of grants under the current Administration has meant that fewer grants are funded by NIH. IDSA supports multi-year awards if they are distributed on a yearly basis, not all at once for a multi-year timeframe, which limits the potential number of grantees. Supported, long-term and multi-year funding is needed to ensure priority federal research has guaranteed resources and funding across adequate periods of time to achieve research objectives.

In conclusion, despite small changes that could streamline federal funding, **IDSA urges OMB to rescind the proposed rule** in order to preserve strong scientific peer review, protect the stability and predictability of federal research and public health funding, and ensure that grantmaking decisions remain grounded in scientific merit and public health need. Maintaining these principles is essential to advancing research, strengthening preparedness, supporting the infectious diseases workforce and protecting the health of communities across the United States.

Thank you for the opportunity to provide comments on this proposed rule. By shifting oversight away from established scientific consensus, this proposal represents a fundamental sea change that risks destabilizing the predictable, multi-year lifecycles essential to modern scientific discovery. Please contact Amanda Jezek, IDSA senior vice president for public policy and government relations, with any questions at ajezek@idsociety.org.

Sincerely,

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President
Infectious Diseases Society of America