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White House Office of Science and Technology Policy
725 17th Street NW
Washington, DC 20500

Submitted electronically to ScientificIntegrityRFI@ostp.eop.gov.

RE: SI-FTAC RFI (86 FR 34064)

The Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) appreciate the opportunity to provide written comments to the White House Office of Science and Technology Policy in response to its Request for Information regarding the current state of scientific integrity processes and practices.

IDSA and HIVMA represent a community of over 12,000 physicians, scientists, public health experts, and other health professionals who specialize in infectious diseases and HIV medicine. Our members work across a variety of healthcare settings, including hospitals, academic medical centers, long-term care facilities, public health departments, publicly funded clinics, and private practice. We support the six principles outlined in the 2009 Presidential Memorandum on Scientific Integrity and urge the Task Force to use these principles as foundation for their work. We are pleased to offer recommendations to the interagency task force of the National Science and Technology Council that we believe will help promote trust in Federal science and strengthen evidence-based policymaking.

1. **The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:**

   - Ensuring transparency should be at the forefront of efforts to promote trust in federal science. This includes the regular and accessible release of data and scientific findings and a commitment to meaningful public input and engagement in the development of regulatory processes.
   - Limit political interference in federal research, which can undermine public health experts and compromise transparency and trust. IDSA has previously commented on proposed Federal COVID-19 data reporting protocols that would have removed the
Centers for Disease Control and Prevention (CDC) as a recipient of data on patients hospitalized with COVID-19.

• Promote the integrity of scientific research by ensuring review boards are composed of subject matter experts committed to transparent and equitable review. Lack of appropriate expertise on Federal advisory boards can undermine trust in federal research processes.

• In cases of Emergency Use Authorizations (EUA) in a public health emergency, regulatory authorities should establish and publicly communicate benchmarks for the receipt of diagnostic, therapeutic, and vaccine EUAs, as well as requirements for receiving licensure after an EUA is granted. Agencies should require the public release of clinical trial data both before a therapy receives an EUA and before it receives subsequent license approval.

• Require clinical trial sponsors to include plans for recruiting Black, Indigenous and other people of color, Latinx communities, children, individuals who are pregnant and breastfeeding, and others who are immunocompromised, including people with HIV, as applicable. Ensure inclusion of individuals living in rural areas and outside of large academic medical centers to ensure more representative trial populations.

2. **Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:**

• Increase and cultivate collaboration and engagement with Federal scientists and contractors working on scientific matters with researchers and physicians from public and private universities and medical schools to facilitate the accurate dissemination of evidence-based scientific data on news and social media. Examples include Dr. Anthony Fauci from the National Institute of Allergy and Infectious Diseases communicating data from peer-reviewed publications in “layman’s terms” on news outlets to provide scientific rationale for Federal health policies during the COVID-19 pandemic. Other examples include physicians who have testified to the United States Congress on the COVID-19 pandemic and on vaccine policy in general. Accuracy and implementation of safe public policy requires the protection of scientific independence during clearance and review processes and the avoidance of political or other improper interference in research or data collection.

• Provide scientific communication training through federally funded grants, which could require explanations for how investigators will ensure the dissemination of data are available in an accessible way to both peers, impacted communities and populations and other constituents.

• Fund and develop mechanisms to enhance accurate scientific communication through social media and other digital platforms to allow for transparent scientific communication and dissemination of important messaging.

• Federal agencies should prioritize the rapid development and release of evidence-based guidance, even in the settings of incomplete science. During the COVID-19 pandemic Federal agency guidelines were often delayed weeks or months, which
resulted in the need for state and local public health agencies to create their own recommendations.

- Support collaborations between the Food and Drug Administration, National Institutes of Health, CDC, and the clinical research community to strengthen and improve clinical trial infrastructure, expand funding mechanisms, and develop better analytical and predictive tools. Federally supported infrastructure should provide an integrated framework to link patients with appropriate trials and encourage large-scale collaboration across many different types of facilities. Expanding clinical trial participation beyond major academic medical centers will also allow studies to reach more diverse patient populations.

- Provide resources within agencies to help researchers and personnel understand effective strategies in communicating science. Resources like the NIH Science, Health, and Public Trust should be supported in working to increase effective communication of scientific research.

- Promote equitable clinical trial design and strategies informed by input from the impacted communities to ensure access to clinical trials for Black, Indigenous and other people of color; Latinx communities; immigrants; and others who are underserved or live on low incomes.

3. **Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:**

- Increase funding support for diversity initiatives that supplement and build on existing programs like the NIH UNITE Initiative, which aims to address structural inequity in the scientific workforce and emphasizes transparent communication with internal and external stakeholders.

- Provide guidance on authorship and settling of authorship debates.

- Provide guidance on commercialization and addressing scientific integrity across the continuum of academia and industry.

- Re-enforce protections for career civil service employees and create an independent body to review candidates for science and technology appointments, including for advisory board appointments, to ensure appointees have the appropriate scientific credentials and expertise.

- Ensure that study section participants include individuals from underrepresented backgrounds and clinician scientists who understand the unique challenges encountered by trainees.

- Provide more funding opportunities for early-stage investigators from underrepresented groups. NIH does this at the predoctoral level with the F31 NRSA Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research mechanism.

- Foster increased collaboration among federal agencies, research institutions and community-based organizations with expertise in health disparities to develop and
inform strategies to improve mentorship programs and career support for underrepresented minorities during training.

4. **Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:**

   - Allocate funding to support educational modules on Responsible Conduct of Research and Rigor and Reproducibility; these teaching obligations are often taxed on research faculty and could benefit from federal support. Develop modules for the training of these topics and host a federal data sharing platform to enable public access to data on a supported server.

5. **Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:**

   - Promote and prioritize the uptake of implementation science, particularly in the development of Federal guidelines and recommendations. By using implementation science, researchers can help bridge the divide between research and practice and bring programs that work to communities in need.

We thank you for the opportunity to help improve the effectiveness of Federal scientific integrity policies and enhance public trust in science. For any questions about our comments, please contact Jaclyn Levy, IDSA Director of Public Policy, at jlevy@idsociety.org or Andrea Weddle, HIVMA Executive Director, at aweddel@hivma.org.

Sincerely,

Barbara D. Alexander, MD, MHS, FIDSA
President, IDSA

Rajesh T. Gandhi, M.D., FIDSA
Chair, HIVMA