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Federation of American Societies for Experimental Biology

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RFI Response - NIH AI Strategy
Attention: Jayanta Bhattacharya, M.D., Ph.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Transmitted electronically to ai-rfi@nih.gov

Dear Dr. Bhattacharya,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the National Institutes of Health (NIH) Request for Information Inviting Comments on the NIH Artificial Intelligence (AI) Strategy NOT-OD-25-117 as published in the NIH Guide for Grants and Contracts on June 3, 2025. We applaud the NIH commitment to seek input on the highest priority actions that should be included in the new AI Strategy. FASEB's comments on the priority policy actions related to AI are provided below.

In December 2024, FASEB completed a publicly available report titled "Recommendations for Generative AI in the Biological and Biomedical Sciences." This report provides comprehensive recommendations on the responsible integration of Generative AI (Gen AI) into biological and biomedical research and is intended to help federal agencies, policymakers, institutions, individual researchers, and other stakeholders navigate the rapidly evolving landscape of Gen AI in scientific research. Our response includes relevant sections of those recommendations aligned with five of the desired categories for input outlined in the RFI.

Strategic architecture: anchoring the new NIH AI plan with foundational themes *(NIH RFI Section 1).*

FASEB recommends that NIH consider the following foundational themes:

- policy and regulation;
- scientific integrity and intellectual property;
- data privacy and security; and
- workforce impact, training, and education.

Our responses to additional sections of the RFI below tie in with one of these four themes. By operating within a framework that considers these themes, NIH can build trust and excellence in biological and biomedical sciences and achieve success in broad implementation of AI to advance human health.

Operational excellence: opportunities to improve NIH customer experiences (grant submission, peer review, engagement) ***(NIH RFI Section 4).***

Guidelines for grant submission, peer review, and engagement.
FASEB encourages NIH to revise guidelines to include AI and Gen AI, and specifically to include:

- Transparency and reporting requirements for AI and Gen AI use in grant applications and research outputs (e.g., publications, data sets, software, and other reports). Given the broad use and integration of AI and Gen AI, it is expected to become impractical to request users divulge all use cases. Certain use cases will be important for disclosure (e.g., data processing and visualization) while other use cases may not be important for disclosure (e.g., writing assistance). Gaining clarity on relevant use cases for reporting will support all stakeholders in ensuring appropriateness, accuracy, and transparency in reporting. Citation styles for Gen AI are already in place, see also MLA and APA style guides.
- The use of or limitations on use of AI and Gen AI by reviewers, program officers, and other stakeholders who have access to confidentially submitted research proposals during the grant application and review.
- Standards for management of AI and Gen AI data sets and software. A set of comprehensive standards for how to manage data sets and software in AI and Gen AI-assisted research in the biological and biomedical sciences will be valuable and avoid further confounding the data management and sharing environment.
- Research integrity considerations. Protocols to ensure rigor and reproducibility of biological and biomedical research involving AI and Gen AI would benefit all stakeholders. This is particularly important for Gen AI given the continuous ongoing evolution of the tools and capabilities, presenting challenges for transparency, explainability, and reproducibility. *See also Reproducibility & Trust below.*

Facilitating & validating AI in healthcare delivery ***(NIH RFI Section 5).***

Preventing harm.
FASEB encourages all stakeholders employing Gen AI to identify use cases in which misinterpretation and reuse of data have elevated levels of potential harm and lead to the adoption of an enhanced level of privacy and security. Particularly in healthcare, emerging Gen AI tools and technology provide an easy path for potential harm to individuals through the accidental inclusion of personally identifiable data. In medical practices, the informed consent process is well-established and serves to protect individuals. At institutions, an institutional review board (IRB) develops procedures to ensure that the appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. Similar approaches could prove useful for such high potential harm use cases of Gen AI and in the initial stages of new tool exploration in healthcare.

Updating data management and sharing plans, security protocols, and data governance protocols.
To further support validation, stakeholders employing Gen AI are encouraged to develop and routinely update data management and security protocols for Gen AI-generated data, including robust data governance plans. FASEB encourages NIH to include Gen AI guidance in their data management and sharing plans. Data management and governance protocols are valuable tools for managing an organization's data effectively and efficiently, and for ensuring integrity and accuracy.

Reproducibility & Trust *(NIH RFI Section 6).*

The connection between scientific integrity and trust is clear. Ensuring scientific integrity is a significant community-wide effort that requires all stakeholders to be fully committed to this central tenet, and applies to use of all research tools, including Gen AI.

Develop and adopt community guidelines for ethical use in research.
FASEB recommends that overarching and application-specific guidelines for the ethical use of Gen AI in biomedical and biological research be developed and adopted broadly by funding agencies, institutions (research, educational, and corporate), and scientific societies. In some cases, AI and Gen AI ethical guidance is already being developed for program-specific applications. Existing infrastructure organizations such as the Committee on Publication Ethics (COPE), STM Association, and Ithaka S+R have released several key guidance documents for use by publications.

Develop and implement appropriate review processes.
To foster reproducibility and trust, NIH is encouraged to develop and implement appropriate review processes for Gen AI-assisted research. These review processes provide for human review and oversight, and would also benefit from the following considerations:

- Check for appropriate and sufficiently detailed disclosure of Gen AI use. Development and implementation of policies and practices that check for Gen AI disclosure, and that also do not seek to penalize researchers for using tools available within the guidelines will encourage greater researcher compliance and ensure scientific integrity.
- In some instances, review processes may need to involve validation of Gen AI generated content or research findings, or a review of whether the data are "clean" for purpose. Whether a validation step is warranted may depend on the type of organization, the use case for the Gen AI-assisted research, or other factors.
- Develop paths for identifying and interrupting potential biases introduced by Gen AI use.
- Consider and evaluate privacy and consent issues, particularly for sensitive data.

- Check against intellectual property issues, ensure proper recognition of software developers, tools, and individual researcher contributions.
- Find ways to measure and evaluate the long-term implications and potential misuse in research involving Gen AI.
- Provide paths for researchers that support pausing or even halting a Gen AI-assisted research project as certain concern thresholds are met. Consider the approach "first do no harm."

Collaborating to develop appropriate community-wide reporting guidelines.
For reporting research findings, FASEB encourages collaborating with key stakeholders to develop community-wide guidelines for specific programs. For reporting research findings, the following items should be addressed:

- Appropriate attribution and authorship for Gen AI-generated content.
- Use of Gen AI in review or decision making.
- Transparency in reporting Gen AI-assisted research (specifically, what types of Gen AI use need to be reported).

Fostering transparency among software developers.
Transparency travels hand in hand with reproducibility and trust, including for Gen AI tools. Software developers are recommended to be transparent and provide credit to underlying publications and datasets used in creating the tool to foster trust, allow proper use case application, and enable monitoring by stakeholders.

Particularly in the sciences, policies are encouraged to require full transparency on how the tool is created, how it works, and the underlying source information, including references to all underlying data and publications used to create the tool. Developing versioning considerations which are subsequently clearly noted in documentation would be beneficial. This is particularly important for Gen AI given the continuous ongoing evolution of the tools and capabilities, presenting challenges for important hallmarks of research integrity: transparency, explainability, and reproducibility. Stakeholders can only trust and use the tools when they can also build processes to ensure scientific integrity is upheld.

Developing tools and platforms for reproducibility.
Federal agencies and organizations are further encouraged to develop tools and platforms for Gen AI reproducibility. FASEB recommends the development and support of open-source tools and platforms specifically designed to enhance the reproducibility of Gen AI-assisted research. These might include:

- Solutions for creating reproducible Gen AI environments (computational).
- Platforms for sharing and reproducing, testing Gen AI-assisted research findings.
- Paths to track the provenance of Gen AI-generated data and research findings.

Respecting intellectual property rights and data.
All stakeholders are encouraged to understand and respect the intellectual property rights and the data of individuals, researchers, and Gen AI software. The intersection of Gen AI and intellectual

property is complex for US policy makers, funding agencies, and all organizations to navigate. Outlined below are several key approaches stakeholders can take to respect intellectual property rights and data throughout the process:

- Gen AI software developers create new intellectual property in the software. However, they do not do so in isolation or without the benefit of the intellectual property of others. Gen AI software is developed by utilizing vast stores of intellectual property rights belonging to others, including individuals and researchers. In this process, there must be understanding of and respect for individual rights and researcher intellectual property rights. Gen AI software developers are encouraged to cite sources, recognize, and respect the intellectual property and other rights of researchers and individuals, and ensure they are properly obtaining the permissions and rights to use the information for the purpose of use. This may seem daunting given the significant amount of information Gen AI software developers use in creating a tool; however, collective opportunities are now growing to make this more achievable.
- Researchers have the right to choose when, how, and under what terms to communicate their research findings, in alignment with long-standing academic freedoms in the US. Publishers should clearly communicate with society partners and researchers, authors upfront (prior to submission) and throughout the publication process to ensure researchers/authors are informed and understand how research outputs might be used to train Gen AI. For all research outputs, publishers, databases, and other reporting mechanisms for research findings would benefit from making clear to researchers what rights they are providing for reuse as it relates to their produced outputs then leveraged in Gen AI software development.
- Individuals and researchers may license and use Gen AI tools to assist in research endeavors, generate new works, and make new discoveries. In this process, there must be understanding of and respect for the Gen AI tool developers' intellectual property rights. Researchers should cite software tools, recognize, and respect the intellectual property rights of Gen AI software developers.
- Gen AI software developers are encouraged to make clear and simple guidelines so that end-users easily understand how the queries and information they input into the tool will be used and provide one-click easy paths for end-users to turn off that access.
- All individuals benefit from the right to data privacy, as addressed in the Data Privacy and Security section of the FASEB report.
- All users are encouraged to be mindful of copyright considerations when using Gen AI – both in terms of content and queries being entered by the user in the Gen AI tool, and the content being generated by the Gen AI tool, including the resources used by the Gen AI tool in development.

Tailoring specific program policies.
Specific programs at organizations require tailored Gen AI policies for certain use cases and communities. For example, at scholarly societies, journals, conferences, and award or grant

programs require additional consideration across a wider group of stakeholders. For institutions (research, educational, or corporate), specific programs may require protocols for approving and monitoring the use of Gen AI in research projects. Across stakeholder groups, providing guidelines for proper attribution when using Gen AI tools, ethical review processes for Gen AI-assisted research, and mechanisms for reporting and addressing misuse or misinterpretation of Gen AI findings are key factors.

Partnerships & ecosystem building *(NIH RFI Section 7).*

Overall collaboration builds faster capacity.
Identifying paths to collaborate across the biological and biomedical sciences ecosystem between institutions and scholarly societies would be advantageous and reduce complexity for communities. Multi-stakeholder adaptive governance and collaboration could help the biomedical and biological sciences community more rapidly build capacity and share resources.

Collaborative development of cohesive guidelines.
Several US federal agencies have released policies that are not yet fully aligned in their approach, which could introduce confusion for researchers. To reduce confusion, FASEB recommends collaboration among federal agencies via an interagency working group coordinated by the newly formed National Artificial Intelligence Advisory Committee (NAIAC) or Office of Science and Technology Policy (OSTP) to develop cohesive guidelines for the use and transparent reporting of Gen AI in federally funded research. The working group can facilitate adoption of consistent approaches across the U.S. infrastructure that also align with global efforts.

Collaborative development of coordinated standards and evaluation of misconduct.
FASEB also encourages NIH to collaborate with other federal agencies to develop uniform coordinated standards for verifying Gen AI-generated data and research findings and to further create resources for stakeholders to leverage regarding Gen AI misconduct evaluation. All organizations should develop processes for verifying Gen AI-generated data and research findings and maintain records. Standards for verifying Gen AI-generated data and research findings will help build trust in the outcomes of research efforts using these tools. Resources that support stakeholders in evaluating Gen AI misconduct would similarly provide necessary infrastructure for use of Gen AI in scientific research. Federal agencies, either via National Institutes of Standards and Technology (NIST) or through another interagency effort, led by OSTP, are encouraged develop and establish standards and resources.

Multi-stakeholder international approaches.
Further, policy makers, federal agencies, and organizations are encouraged to consider, when feasible, multi-stakeholder and international approaches. Gen AI developments and applications in biological and biomedical sciences are already spanning geographic borders. Instead of each nation developing individual approaches, multi-stakeholder and international approaches could allow more rapid building of capacity and shared resources, requiring fewer overall added resources.

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Conclusion and Workforce Development

Although not specifically outlined in the RFI, the rapid pace of development of Gen AI tools and their potential applications in the biological and biomedical sciences necessitates a comprehensive end-to-end workforce approach to training and education. The workforce lacks an understanding of Gen AI that would help them effectively utilize Gen AI tools and identify the best use-case opportunities, within the complex parameters around data privacy, security, sensitive information, and intellectual property. Upholding research integrity and developing critical thinking skills are companions to the need for Gen AI training in support of a stronger workforce.

FASEB encourages NIH to provide resources for the development and implementation of multi-tiered Gen AI training programs and toolkits to address the diverse needs of researchers at different career stages and roles. The need extends beyond the traditional K-12 or undergraduate educational training and must include researchers at all career stages and their differing needs. Developing the Gen AI skillset of the US biological and biomedical sciences workforce in academic and research institutions, non-profits, and corporations is a priority for the US workforce to thrive.

Thank you for providing the research community with the opportunity to review and comment on the development of the NIH AI Strategy.

Sincerely,

Eric E. Kelley, PhD

FASEB President