LEADING IN GOLD STANDARD SCIENCE

An NIH Implementation Plan

National Institutes of Health
Turning Discovery Into Health

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Gold Standard Science at NIH

The mission of the National Institutes of Health (NIH) is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. At the heart of this mission are the principles of gold standard science and NIH remains steadfast in our commitment. NIH has long supported programs, policies, and initiatives grounded in robust and rigorous science that are foundational to success.

This implementation plan outlines NIH's key accomplishments to date in delivering gold standard science to the American public and presents a transparent vision for the road ahead. Public input and accountability are embedded throughout NIH processes, reinforcing the credibility of our science and findings. These efforts foster an environment that advances the highest quality science to improve the health of all Americans.

"Gold standard science isn't just what we strive for, it is embedded in everything we do, from the research we support to the policies and programs we create."

- Jay Bhattacharya, NIH Director

Implementing Gold Standard Science at NIH

In 2025, the Executive Order (EO) on Restoring Gold Standard Science and Agency Guidance for Implementing Gold Standard Science in the Conduct and Management of Scientific Activities directed NIH and other federal agencies to implement principles of gold standard science in the conduct and management of all aspects of their scientific activities. NIH strives for scientific excellence and welcomes the opportunity to reaffirm its continued commitment to this goal.

GOLD STANDARD SCIENCE IS...

- Reproducible
- Transparent
- Communicative of Error and Uncertainty
- Collaborative and Interdisciplinary
- Skeptical of Its Findings and Assumptions
- Structured for Falsifiability of Hypotheses
- Subject to Unbiased Peer Review
- Accepting of Negative Results as Positive Outcomes
- Without Conflicts of Interest

In response to the EO and guidance, and in accordance with its continued commitment to promoting the highest standards of scientific integrity, NIH has developed this inaugural plan to highlight success and provide a roadmap for the future. What follows is a description of exemplary policies, activities, and initiatives across NIH that demonstrate the agency's commitment to the tenets of gold standard science.

Tenets of Gold Standard Science

NIH's portfolio spans the biomedical research[1] spectrum, from basic to translational to clinical research. As such, the nine tenets of the EO are inherently intertwined and richly underscored throughout NIH's current and planned research activities. Many NIH policies and programs crosscut more than one tenet. Additionally, within and across the tenets, NIH develops training and resources for the workforce, funded researchers, and peer reviewers to ensure adherence and awareness of evolving requirements. Therefore, certain activities will intentionally appear in multiple tenets across this plan.

I. Reproducible

NIH continues its dedication to advancing reproducible and replicable biomedical sciences, as illustrated by its prioritization of new and updated policies, programs, and processes, and increased training opportunities. Importantly, reproducibility and replicability are not one in the same, but equally important to advancing gold standard science.

- *Reproducibility*: the ability of independent researchers to test a hypothesis through multiple methods and consistently achieve results that confirm or refute it, ensuring findings are generalizable and robust across different approaches.
- *Replicability*: the ability to perform the same experiment or study using the same methods and conditions to achieve the same result.

[1] For the purposes of this report, the term biomedical is used broadly to include biological, behavioral, and social scientific perspectives.

Current Efforts

Since FY16, NIH has updated its grant application and review processes to enhance the reproducibility of research findings through increased scientific rigor and transparency. These updates apply to all peer-reviewed NIH funding mechanisms and other transactions. In addition, NIH maintains a public facing site to provide the public with information about its efforts to enhance rigor and reproducibility in scientific research and to embed these aspects in NIH grant applications and progress reports. NIH also provides resources and training on many aspects of rigor and reproducibility, including sex as a biological variable, research methods, reviewer guidance, and more. Institutional Research Training Grants require that all training programs provide trainees with education and experience in a variety of rigorous and reproducible scientific approaches.

In FY23, NIH updated its Guidelines and Policies for the Conduct of Research in the Intramural Research Program (IRP), to include Scientific Rigor and Reproducibility as a core function, outlining four areas of focus: assessment of prevailing knowledge to identify strengths and weaknesses in prior research and any gaps in knowledge; application of scientific methodology to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and dissemination of results; consideration of biological variables that can influence experimental design and scientific methodology; and validation of reagents, chemicals, biologics, and tests used in the research. The NIH IRP also curates a selection of Reproducibility Training modules on relevant topics, as well as additional resources and articles, to define best practices for designing experiments and how to apply those practices in the real-world research environment.

Since FY24, NIH has launched several new research strategies focused on enhancing the reproducibility and replicability of biomedical research and novel technologies, such as the NIH Common Fund's Replication to Enhance Research Impact Initiative (Replication Initiative). The Replication Initiative supports replication efforts for preclinical, translational, and technology development research studies from NIH Common Fund programs and NIH-supported research across different scientific research areas. Genomics research is an area that is ripe for reproducibility efforts, thanks to the vast amounts of multimodal data and methodology available, such as machine learning and artificial intelligence (ML/AI). For example, ML/AI Tools to Advance Genomic Translational Research (MAGen) researchers are leveraging existing multimodal genomic and non-genomic data, and the ML/AI tools will be cross validated in genomic translational research settings to ensure the robustness and generalizability of the tools for translational purposes.

Importantly, NIH believes that making the results of NIH-funded research available is key to advancing transparent, rigorous, and reproducible research, as illustrated by its Data Management and Sharing Policy, Genomic Data Sharing Policy, Public Access Policy, Dissemination of NIH-Funded Clinical Trial Information Policy, and other sharing policies. To ensure NIH supported data are generated in accordance with the highest standards, NIH trains and supports researchers in their gold-standard data sharing efforts, such as advancing FAIR (findability, accessibility, interoperability, and reusability) data principles. NIH also maintains a robust modern data resource ecosystem made up of biomedical data repositories and knowledge bases, including a repository of common data elements (CDEs) to standardize the way data is collected and make data from

different studies more interoperable. NIH also funds databases of standard data elements for specific areas of biomedical research, such as genomics. Moreover, TRUST (Transparency, Responsibility, User Focus, Sustainability, and Technology) principles are emphasized in the data resource ecosystem to build trustworthiness and ensure long-term accessibility. Maintaining scientific data in publicly accessible repositories facilitates replication and supports reproducibility.

Planned Efforts

NIH continuously seeks new strategies for advancing reproducible and replicable biomedical approaches, and is planning to develop new, targeted funding mechanisms and programs that foster culture change across the research enterprise. NIH is planning new efforts to support reproducing and replicating data and research results, including those focused on sharing negative or null results. NIH is also identifying areas in which more tools are needed to deliver replicable, translatable, and efficient results such as human-based research technologies and expansion of efforts of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

Programs throughout NIH are also working to incorporate research specific priorities focused on rigor to strengthen translatability of research outcomes. For example, NIH is developing Reproducibility and Integrity Guidance to Optimize Research (RIGOR) for Dietary Supplements to strengthen the experimental design and methodological rigor applied in NIH-funded dietary supplement and related nutrition research. A current challenge in this area of research is limitations in research comparability and translatability when the information characterizing a natural product is incomplete. The RIGOR for Dietary Supplements activities may include creating best practice guidance and training resources, prioritizing research funding opportunities, or enhancing the review of NIH grant applications.

II. Transparent

As a publicly funded institution, NIH strives to exemplify principles of transparency and works to bolster its efforts to usher in an era of radical transparency. Transparency efforts can be found throughout the research lifecycle, starting with peer review, public posting of all active awards, requirements for sharing research data and results, and more.

Current Efforts

One of the core values of NIH peer review is transparency. Investigators can view established, published review criteria to understand the factors by which their grant applications are evaluated for scientific and technical merit. NIH also publicizes descriptions of standing review panels, the rosters of individuals who participate on review panels, and information on each funded grant. Beginning January 2025, scoring factors and the review process were streamlined into the Simplified Peer Review Framework to address the complexity of the review process and potential for reputational bias.

After the decision to fund a project is made, NIH provides the public with comprehensive and detailed information about each individual NIH grant, project, research contract, and intramural project through the NIH RePORTER database. For each grant or project, NIH RePORTER provides a

description of the research, details on the principal investigator and organization, funding information, as well as links to associated scientific publications, media reports, patents, and other outcome data. In the Research Portfolio Online Reporting Tools (RePORT) page, NIH provides NIH funding data, including data by research topic or category (Categorical Spending) and Awards by Location. The NIH Data Book, located on the RePORT page, provides information on success rates, the NIH-supported research workforce, small business grants, and other topics. This information enhances transparency and enables the public to assess the characteristics, comprehensiveness, and the results of NIH-funded research.

Once the research is complete, the NIH Policy for Data Management and Sharing establishes the expectation that NIH-supported scientific data should be maximally shared for the public good. In addition to the general policy, NIH has established several field-specific data management and sharing policies, including policies for registering and submitting results from NIH-funded clinical trials and for sharing genomic research data. To provide unrestricted access to scientific results and publications produced by NIH-funded investigators, the strengthened NIH Public Access Policy establishment date was accelerated. The policy is now in effect as of July 2025. Additionally, NIH facilitated the development of a consensus set of principles and guidelines for reporting preclinical research to facilitate reproducibility and transparency.

To promote transparency and sharing of research tools, NIH expects funding recipients to ensure that unique tools developed from NIH-funded research are available to the research community as outlined in the Research Tools Policy. To ensure access to results and publications, NIH established the Public Access Policy which requires manuscripts accepted for publication in a journal to be submitted to PubMed Central upon acceptance for publication, for public availability without embargo upon the Official Date of Publication.

Through the National Library of Medicine (NLM), NIH facilitates transparency and public access to scientific results through www.clinicaltrials.gov, where people can learn about clinical studies from around the world. This database includes trials supported not only by NIH but by many other funding agencies as well and requires federally-supported trials to report results to the public, including negative or null findings. NLM also supports PubMed, a free resource providing comprehensive search and retrieval of biomedical and life science literature. The PubMed database contains more than 38 million citations and abstracts.

NIH also strives to practice transparency in our meetings and decision-making activities. The advisory councils of Institute and Centers (IC) and the advisory groups to the NIH Director, including the Advisory Council to the Director (ACD), provide live videocasts and associated materials for open meetings so that interested parties may listen to all advice shared to IC leadership or the NIH Director, respectively, on major decisions on plans and policies affecting the NIH.

Planned Efforts

NIH recognizes much more can be done to embed transparency in research. For example, current efforts surrounding the biosafety and biosecurity of life sciences research are being reviewed to enact new processes for trust and transparency. After an assessment of rigor and transparency of animal research, an ACD Working Group recommended the use of Animal Research: Reporting of In

Vivo Experiments (ARRIVE) guidelines. The ARRIVE Essential 10 describes the basic minimum information to include in a manuscript that allows the reader to assess the reliability and findings of a study (e.g., sample sizes, outcome measures, descriptive statistics). The proposed adoption of these principles as an expectation at NIH will further increase transparency and openness in animal research.

NIH is also working with its federal partners to provide consistency in reporting research and financial disclosures through the adoption of a Common Form. NIH will be seeking to leverage this work to strengthen trust in research processes and results.

III. Communicative of Error and Uncertainty

The process of translating research findings into improved health outcomes is predicated on the quality, objectivity, utility, and integrity of information disseminated to the public. This includes the clear, precise, and accurate disclosure of limitations, variability, and potential sources of error or limitations in measurements or research findings. NIH utilizes a variety of approaches to ensure that the information disseminated clearly describes the intended research scope and reflects constraints, assumptions, and the uncertainty of its funded findings.

Current Efforts

In research reporting, NIH ensures that disseminated information meets the standards of quality set forth in the Office of Management and Budget (OMB) Information Quality Guidelines, the Department of Health and Human Services (HHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public, and the NIH Information Quality Guidelines. Additionally, NIH adheres to the HHS Guidelines on the Provision of Information to the News Media to communicate scientific research that is accurate, timely, and of the highest integrity standards.

In the NIH IRP, scientific research is guided by a comprehensive collection of Guidelines and Policies for the Conduct of Research. This guide covers in detail topics including scientific record keeping, data management, authorship, publications, mentoring, collaborations and team science, scientific rigor and reproducibility, peer review, scientific integrity, conflicts of interest, animal care and use, ethical leadership and management, and more. The guide covers the entire research process, from formulating a question or hypothesis to designing robust and statistically valid experiments and studies, to developing research protocols, and generating, analyzing, and interpreting data.

Planned Efforts

NIH policies have always supported the public dissemination of research. However, academic freedom matters most in cases where scientists are pursuing evidence that may be perceived as inconvenient or objectionable. By prioritizing academic freedom across the agency, NIH is working to strengthen public trust.

NIH is drafting a new chapter on gold standard science for the 2025 revision of the comprehensive collection of Guidelines and Policies for the Conduct of Research in the IRP. NIH is also embarking on a review of policies and practices within its IRP to further promote academic freedom to ensure NIH scientists are guaranteed the freedom to engage in open, academic discourse without fear of

official interference, professional disadvantage, or workplace retaliation. Critical evaluation of evidence and a willingness to challenge the conventional thinking are essential for ensuring scientific rigor, meaningful results, and communication of those results. NIH continues to encourage scientists to freely communicate their scientific findings to the public and through scientific journal publications, reports, and conferences. NIH is exploring plans to shift its process for scholarly works from approving scientific content or findings to reviewing exclusively for policy and regulatory compliance. Processes around media engagement are also being modified to ensure preservation of academic freedom.

IV. Collaborative and Interdisciplinary

NIH champions the use of effective collaborations for the advancement of scientific research. From funding cross-disciplinary projects to collaborating with other federal agencies and private entities, NIH continues the mission of addressing the nation's top health and scientific concerns through innovative partnerships.

Current Efforts

NIH encourages researchers to form interdisciplinary teams to bolster the science and advance the mission of improving public health. The agency itself participates in many exemplary collaborations across and outside the federal government with targeted goals that advance biomedical research. The National Collaborative on Childhood Obesity Research (NCCOR) is a public-private partnership that brings together NIH, the Centers for Disease Control and Prevention (CDC), U.S. Department of Agriculture (USDA), and the Robert Wood Johnson Foundation in efforts to reduce childhood obesity. NIH has also partnered with the National Science Foundation (NSF) National AI Research Resource Pilot (NAIRR Pilot), which seeks to create a shared national research infrastructure, providing U.S. researchers with access to responsible and trustworthy AI resources for conducting research. The NIH Bridge to Artificial Intelligence (Bridge2AI) program brings together technological and biomedical experts, as well as social scientists to generate datasets that are ready for use for ML/AI technology.

Meaningful connections between the clinicians and professionals who work directly with America's patient population are also critical for improving healthcare. The NIH Undiagnosed Diseases Network (UDN) leverages a nationwide network of clinicians and researchers using both basic and clinical research to uncover the underlying disease mechanisms associated with rare and undiagnosed conditions. With the Foundation for the NIH and in partnership with industry and non-profit organizations, the Accelerating Medicines Partnership® (AMP®) crosses 16 NIH ICOs to accelerate new and effective patient therapies for diseases including Alzheimer's disease, Parkinson's disease, and schizophrenia, among others.

Within HHS, there are many opportunities for collaborations that capitalize on the strength and expertise of the various Operating and Staff Divisions. To keep record of these partnerships and provide opportunities to capitalize on them, NIH produces an annual report of all collaborations with other HHS agencies, known as the HHS Collaborations Report. This report, also shared publicly, includes details of the nature and frequency of collaborations carried out with specific agencies or divisions. Within the agency, NIH also provides a record of collaborations between the ICOs to foster effective internal partnerships and co-funding opportunities.

Planned Efforts

To further maximize the opportunity for cross-agency collaboration, NIH plans to launch new collaborative initiatives that directly address urgent research and health issues of today. In May 2025, NIH announced a landmark partnership between NIH and the Centers for Medicaid and Medicare Services (CMS) to enable research around the root causes of autism spectrum disorder. In collaboration with the HHS Office of the Chief Data Officer and partner agencies including CMS, ARPA-H, CDC, and FDA, NIH is building a Real World Data Network that will support initiatives to study autism, chronic disease, and other key public health concerns. NIH will also join the U.S. Food and Drug Administration (FDA) to form the Nutrition Regulatory Science Program, a joint innovative research initiative to implement and accelerate a comprehensive nutrition research agenda to inform effective food and nutrition policies to help make Americans' food and diets healthier. NIH also intends to prioritize and fund human-based research technologies and expand the efforts of the multi-agency ICCVAM.

V. Skeptical of Its Findings and Assumptions

NIH aims to continually build a culture of constructive skepticism in which scientific findings and assumptions are open to evaluation and critical assessment. Through robust review of scientific approaches and unbiased evaluation of agency policies and guidance, NIH will advance open-minded and impartial science.

Current Efforts

Throughout the research cycle and at all levels of consideration, NIH processes and policies allow for challenges to scientific conclusions. As part of the priority-setting process, the establishment of strategic plans for all NIH ICOs challenge them to evaluate their respective scientific field for gaps or weaknesses in knowledge and set priorities to address them. Peer review requires the ideas and findings of investigators to be challenged by other experts in their immediate and proximal scientific research fields. The NIH Public Access Policy requires that authors who receive NIH funding and submit peer reviewed manuscripts accepted for publication in a journal make their work available to the public without embargo through PubMed Central. Ensuring public access of results supported by taxpayer funds allows for scientists and the public to further examine study design, underlying assumptions, and results.

Testing the replicability and reproducibility of scientific findings also pushes scientists and their respective fields to exercise skepticism towards research results. As mentioned in the Reproducible section, NIH supports the conduct of replication studies through programs such as the Replication Initiative. Through this initiative, NIH will support partnerships between independent contract research organizations and researchers to replicate important lines of research and validate novel technologies.

Planned Efforts

Critical to this tenet and referenced previously, NIH has announced a new, comprehensive review of policies and practices within its IRP to ensure that academic freedom is the rule, and not the exception. Academic freedom allows scientists to freely express skepticism of findings and propose alternate views and methods. NIH will also ask scientists to evaluate and critique the

efficacy of agency policies through a new Pilot NIH Science of Science Scholars Program. This program provides the opportunity for experienced "science of science" researchers to analyze internal NIH administrative data to evaluate NIH's contributions and impact to biomedical research, optimize NIH's investments, and ensure scientific quality, rigor, and reproducibility.

VI. Structured for Falsifiability of Hypotheses

NIH's priority setting processes provide strong support for hypothesis-driven research while balancing opportunities to support other forms of innovative and high-risk research (e.g., discovery science). Effective falsifiability requires researchers to formulate precise, testable hypotheses, design experiments with measurable outcomes, and employ rigorous methodologies—such as controlled experiments, randomized trials, or advanced statistical tests—to systematically challenge predictions. Importantly, NIH leverages the complementary roles of hypothesis-generating and hypothesis-driven science to achieve these aims.

Current Efforts

As stated in the Reproducible section, NIH updated its grant application and review processes to enhance the reproducibility of research findings through increased scientific rigor and transparency. This policy requires grant applications to clearly outline, and be evaluated on, 1) the rigor of the prior research, 2) rigorous experimental design for robust and unbiased results, 3) consideration of relevant biological variables, and 4) authentication of key biological and/or chemical resources. Increasing emphasis on these areas clarified NIH's long-standing commitment to funding the best and most rigorous science and ensured that all grant applications were held to the same gold science standard. NIH resources and training on rigor and reproducibility help researchers design research questions, hypotheses, and experiments to 1) allow for rejection after thorough testing and evidence generation, and 2) support reviewers in their fair and consistent evaluation of grant applications.

In addition to NIH's FY23 updates to its Guidelines and Policies for the Conduct of Research in the IRP—which emphasizes the importance of research records documenting the entire research process from formulating research questions and hypotheses to interpreting data—NIH also provides training on the Responsible Conduct of Research (RCR). To bolster the significance of RCR principles in the next generation of scientists, all NIH intramural researchers are required to participate in ongoing RCR training, and all NIH research training programs are required to consider including instruction on RCR. RCR training topics transect many gold standard science tenets and include areas such as research misconduct and questionable research practices, scientific rigor and reproducibility, peer review, conflicts of interest in research, collaborative science, and others. Training on these topics is critical to ensuring the next generation of scientists are equipped to generate high quality research and communicate their findings.

Additionally, NIH supports the NIH Preprint Pilot to make preprints resulting from research funded by NIH available via PubMed Central and, by extension, PubMed. Preprints are complete and public drafts of scientific documents not yet certified by peer review. By increasing the discoverability of early NIH research results, this pilot is speeding the dissemination and enhancing the rigor of research. The availability of preprints invites feedback and discussion to help improve the work prior to peer review and publication.

Planned Efforts

In FY25, FDA and NIH launched the Modernizing Research and Evidence (MoRE) Glossary for more than 40 clinical research terms and definitions used to describe design, methods, analysis, and interpretation of innovative clinical study designs, including studies using real-world data for FDA-regulated medical products (i.e., drug, device, or biologic). The goal of this collaboration is to facilitate efficient, rigorously-designed clinical studies of drugs, devices, and biological products. By providing consensus for terms and definitions, this glossary promotes communication and the use of specific terms allowing for more effective falsifiability of hypotheses. FDA and NIH will continue to collaborate and explore opportunities to build out this effort and develop additional consensus definitions for clinical research terms to aid in the innovation of clinical study designs that support scientific, patient, clinical, and regulatory decision-making.

VII. Subject to Unbiased Peer Review

NIH has a complementary suite of efforts to ensure that it funds the highest quality research free from influence or bias. By prioritizing unbiased peer review of research proposals and manuscripts that report the results of federally-funded research, NIH can continue to protect the public's investment in biomedical research from bias and build public trust.

Current Efforts

Approximately 80 percent of NIH's budget in biomedical research supports extramural researchers at institutions in every state in the country. Given the size and breadth of this investment, NIH has a robust infrastructure to ensure unbiased peer review and procedures to address allegations of biased peer review. The core values of NIH peer review are expert assessment, transparency, impartiality, fairness, confidentiality, security, integrity, and efficiency. These values drive NIH to seek the highest level of scientific and ethical standards, and form the foundation for the laws, regulations, and policies that govern the NIH peer review process. Peer review at NIH proceeds via a two-tiered system involving initial peer review for scientific and technical merit and subsequent review by National Advisory Councils or Boards that recommend applications for funding, with consideration of the funding ICO mission and research priorities. Both levels of the NIH peer review process involve the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to NIH (see section 492 of 42 U.S.C 289a (Public Health Service Act) and Federal regulations).

As mentioned in the Transparent section, NIH recently implemented the Simplified Framework for NIH Peer Review Criteria, which became effective on January 25, 2025, for most research project grants. To ensure robust adoption by NIH staff, study section chairs, and reviewers, the Center for Scientific Review (CSR) trained staff extensively on the simplified criteria and hosted webinars for all study section chairs. In addition, scientific review officers (SROs) met with reviewers to ensure continued consistency, quality and integrity of review. NIH holds periodic training workshops for SROs on review integrity which are recorded and available to staff on demand. Additionally, NIH has made reviewer guidance publicly available to ensure transparency for applicants across the research enterprise.

To ensure that peer review at NIH maintains its rigorous standards, NIH has multiple mechanisms to receive reports of integrity or fairness concerns related to peer review. Additionally, both non-

federal peer reviewers and federal peer reviewers must disclose any conflicts of interest prior to participation in the review process.

NIH is also dedicated to ensuring that the science conducted within its walls is robust and reviewed with parity. Intramural research at NIH is reviewed by the Federal Advisory Committee Act (FACA)-sanctioned, external Board of Scientific Counselors (BSC) that assess the performance of the intramural scientists and the quality of their research programs to advise their Scientific Directors and Clinical Directors. The criteria used are similar to those used for extramural science reviews: significance, approach, innovation, environment, support, investigator training, productivity, and mentoring, with rigor and reproducibility required to be addressed by each principal investigator reviewed. The Scientific Directors and Clinical Directors are senior investigators or clinicians who exemplify judicial leadership within their ICO and are chosen based on their scientific and administrative management and ethical leadership. Review and evaluation of intramural programs for each principal investigator at each ICO is conducted at least once every four years by the BSC.

Planned Efforts

In March 2025, NIH announced a new plan to centralize the initial peer review process for all applications for grants, cooperative agreements, and research and development contracts solely within CSR. Centralizing peer review will make NIH review more efficient and minimizes appearance of preferential treatment depending on which IC manages review.

NIH is also developing a Conflict of Interest (COI) tool for NIH staff charged with screening potential reviewers that gathers publicly available information such as authors on publications and patent holders in combination with data already in NIH systems. This tool will allow staff to more thoroughly vet reviewers for potential COIs before making assignments to specific applications. In addition, NIH has an active Review Integrity Committee which will host interactive workshops on specific review integrity topics tailored to address current issues.

VIII. Accepting of Negative Results as Positive Outcomes

Dissemination of null or negative results is vital for scientific progress and accurate assessment of cumulative evidence. NIH will prioritize developing new resources to instill culture change throughout the biomedical enterprise to promulgate the view of negative results as valuable scientific outcomes.

Current Efforts

In FY23, the NIH Policy for Data Management and Sharing, mentioned in both the Reproducible and Transparent sections of this report, went into effect. Oftentimes, due to publication figure constraints and word limits, negative or null results are not clearly included in the final peer-reviewed publication. By setting the expectation for the use of established data repositories to share scientific data regardless of publication status, NIH is ensuring its researchers transparently report all outcomes—including null and negative results—and the methods, analyses, and limitations of those outcomes.

In addition, the NIH Preprint Pilot, mentioned in the Structured for Falsifiability of Hypotheses section, makes it easier for researchers to share early results from NIH-supported research that

may include negative or null results that otherwise are unlikely to receive favorable peer review. By increasing the discoverability of early NIH research results, this pilot is speeding the dissemination and enhancing the rigor of research.

Planned Efforts

In FY24, NIH released a Request for Information on Potential Solutions for Reducing Publication Bias Against Null Studies to solicit public input on the barriers and solutions to reducing publication bias (i.e., the preferential dissemination of statistically significant or otherwise exciting studies) in biomedical research. After reviewing the responses received, NIH plans to launch new, ground-breaking initiatives to solve this multi-faceted issue.

IX. Without Conflicts of Interest

Managing real or apparent COI among NIH funded scientists and its staff is vital to the integrity of the biomedical research enterprise. NIH strives to assure the public of its commitment to advancing unbiased science and supports this effort by requiring disclosures of relevant COIs and ensuring the scientific community and its staff operate with the highest ethical principles.

Current Efforts

To guard against real or perceived COIs within the extramural scientific community, NIH requires recipient institutions and their investigators (except Phase I SBIR/STTR applicants and recipients) to fully comply with all Financial COI requirements. NIH requires the disclosure of all sources of research support, foreign components, and financial conflicts of interest for senior/key personnel on research applications and awards. NIH uses this information when making its funding decisions to determine if the research being proposed is receiving other sources of funding that could be duplicative, has the necessary time allocation, or if financial interests may affect objectivity in the conduct of the research. These requirements must be met throughout the life of an NIH grant, which is critical to maintaining full transparency.

NIH has numerous policies in place to guard against COIs within its staff, including NIH intramural scientists. NIH maintains an Ethics Program and NIH employees who have financial interests, including outside employment, stocks, and other financial holdings of their own or financial interests of a close party imputed to them, must disclose any conflict and work with the Deputy Ethics Counselor or Ethics Coordinator to obtain a waiver or authorization, or be disqualified from participating in particular matters concerning the outside entity. For the extramural scientists it funds, NIH requires recipient institutions and their investigators (except Phase I SBIR/STTR applicants and recipients) to fully comply with all Financial COI requirements.

As members of the executive branch of the U.S. Government, NIH employees, including intramural scientists, are subject to the Standards of Ethical Conduct for Employees of the Executive Branch. In addition, NIH intramural scientists are also subject to numerous Federal regulations and requirements to safeguard scientific integrity in intramural research activities and are expected to integrate ethical principles into the design, conduct, and dissemination of biomedical research. These same principles are held when NIH selects individuals to serve on its Federal Advisory Committees (FACs). Members are generally appointed as Special Government Employees and are required to disclose real or apparent conflicts related to their service.

To manage COIs that may arise during NIH peer review of grants and contracts, NIH requires non-federal peer reviewers and federal peer reviewers to disclose potential COIs prior to participation in the review process of grants, cooperative agreements, and fellowships, and they must also certify no new COIs have arisen after completion of their review. Non-federal peer reviewers and federal peer reviewers reviewing contracts must also follow the same disclosure process. Additionally, the NIH Policy for Managing Conflict of Interest in the Peer Review of Concepts and Proposals for Research and Development Contract Projects governs the management of COI, prejudice, bias, or predisposition on non-federal reviewers and federal reviewers in the peer review of project concepts and proposals submitted to NIH for research and development (R&D) contract projects.

To support NIH staff and scientists in understanding their responsibilities related to performing their duties free of COIs and with the highest ethical principles, NIH provides RCR training. All NIH intramural scientists are required to participate in ongoing RCR training, which includes a NIH Research Ethics Course and Annual Ethics Case Studies. RCR training topics are interrelated to many of the tenets of gold standard science including COI in research. FAC members are also required to complete a web-based ethics training module, which covers financial disclosure, COI, and misuse of positions.

Planned Efforts

Promoting trust and transparency in the research NIH supports requires management and reporting of research financial COIs. With other federal partners, NIH is actively exploring strengthening mechanisms for researchers to disclose and share their financial relationships to mitigate potential COI to promote a shared culture of transparency.

The NIH Ethics Program will continue to update its training modules for staff, which include its new employee ethics training and its annual ethics training for all NIH federal employees.

Defining Our Success

Evaluation of our programs, policies, and initiatives is foundational to ensuring NIH continues to deliver results for the public. Current and planned NIH initiatives will be periodically assessed for adherence to the nine tenets via initiative-specific retrospective or prospective evaluation. Evaluation metrics will be augmented with several composite measure indexes that are under development.

Evaluation Strategy

NIH may rely upon several frameworks to guide its evaluation activities: the *simplified Consolidation Framework for Implementation Research (CFIR*)[2] to guide evaluation of the pre-

[2] Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated *Consolidated Framework for Implementation Research* based on user feedback. Implement Sci. 2022 Oct 29;17(1):75.
n.b. CFIR is a comprehensive typology of constructs likely to influence the implementation of Evidence-Based Innovations (EBIs): (a) intervention characteristics, (b) outer setting, (c) inner setting, (d) characteristics of individuals, and (e) the implementation process.

implementation phase; the *Reach Effectiveness Adoption Implementation Maintenance* (RE-AIM)[3] framework to guide evaluation of the implementation and post-implementation phases; and Proctor's *Implementation Outcomes Framework (IOF)*[4], a framework for translating research into practice and planning programs to improve the odds for successful implementation in "real-world" settings. The use of these frameworks will enable NIH to evaluate adoption, implementation fidelity, and acceptability of aspects of gold standard science as well as sustainability and scalability after initial implementation.

Evaluation Transparency

NIH will post annual updates of evaluation progress and findings online, sharing widely with public audiences. Additionally, through channels such as evaluation presentations at local, regional, and national medical and public health professional meetings, NIH plans to disseminate information on its efforts to support the translation, communication, and incorporation of the nine gold standard science tenets while informing the public of its progress in affirming gold standard science.

Evaluation Structure

Below is a sample evaluation planning table for tenet 1, **Reproducible,** subject to refinement based on feasibility, scoping, and resources.

Reproducible
Objectives: Prioritize disciplined scientific methods and experimental design to advance reproducible and replicable science.
Outcomes: NIH funded studies have clear, standardized, and justifiable protocols; comprehensive documentation; robust statistical methods; adequate sample sizes; validated methodologies; and appropriate controls.
Measures: Grant applications, CSR peer review submissions, and publications.
Metrics: Percentage change in the number of NIH-funded studies meeting protocol standards; peer review scores on experimental design; number of studies with validated methodologies, and appropriate controls; and number of funded studies that are validated via replication studies.
Methods: Content analysis of grant applications, peer review comments/scores, published research, training programs for researchers and reviewers, and related validation studies. **Analytic Tools:** Predictive modeling—classification/cluster/time-series models, workflow analysis, data and text mining.
Data Sources: PubMed Central (PMC), eRA Commons, NIH Center for Scientific Review (CSR), NIH RePORTER, QVR
Mechanisms: Development of guidelines for standardized protocols on comprehensive documentation, robust statistical methods, adequate sample sizes, validated methodologies, appropriate controls, and trainings for researchers and reviewers.

[3] Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999 Sep;89(9):1322-7.

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Concluding Remarks

NIH remains committed to using a gold standard science approach to strengthen public trust and responsibly drive advances in biomedical research that produce tangible benefits for the American public. In planning, implementing, and evaluating NIH's research and training programs and policies, NIH will remain accountable to the American people, providing updates on progress and outcomes. We look forward to working across the U.S. government and in partnership with our stakeholders and the public to deliver on this vision.