ENDOCRINE SOCIETY
Hormone Science to Health

Rigor and Reproducibility (32767 characters max)

Rigor and reproducibility are essential for advancing research and transforming science into discoveries that benefit public health and build trust in science. The National Institutes of Health (NIH) should revise the NIH Data Management and Sharing Policy to create standard operating procedures for the management and sharing of data, guide the review of data and data analysis, and strengthen data integrity practices.

All NIH intramural and extramural researchers supported by training grants or career development awards are required to take Responsible Conduct of Research (RCR) courses. NIH should consider expanding RCR training to all researchers (graduate students, postdocs, staff, PIs) to develop and enhance their foundational knowledge of experimental design, replication, and reproducibility.

A cultural shift is needed in the academic system to incentivize replication studies. The current tenure system rewards scientific advancements. Novel discoveries and related publications are what help protect a Principal Investigator's (PI's) job security and lead to promotions. The "publish or perish" mentality discourages replication studies as the publication of "negative" or non-innovative data is not seen as something that will help advance their research or their career. Incentives and rewards must be built into the grant application system to consider replication in the context of rigor and reproducibility and shift the culture of the tenure system.

Implementing plans to validate previously published scientific data and to generate novel data are two important but separate goals that require different incentives and rewards. To support ongoing and future research efforts, NIH should consider providing PIs with additional financial support for additional materials and other costs associated with replicating their own scientific findings when needed. While the onus is on the PI for ensuring all lab personnel are adhering to best practices in the lab to maximize rigor and reproducibility efforts and avoid scientific misconduct, the NIH should consider providing workshops and resources to help PIs and their institutions with training to maintain consistency across the U.S. Evaluation of plans for addressing rigor, reproducibility, and transparency should be underscored through the grant review process.

To address the reproducibility of previously published fundings, NIH should create a dedicated funding stream (such as a new R award) to support the materials and personnel needed for the replication of high-impact findings and should coordinate which research findings are prioritized for replication to avoid duplicative efforts. To incentivize researchers to replicate and publish replication studies of previously published studies, NIH should partner with high-impact journals to provide a pathway for publications of replication efforts that help researchers build prestige. Building upon NIH's desire to support and expand data sharing among researchers, NIH could require that all raw

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data be uploaded for sharing, except when disclosure of such data would potentially identify human subjects. Supplemental data repositories can be cost limiting for journals. NIH should find a way to partner with journals to support these extra costs. It is important to note that replication of clinical trials may be challenging, particularly for studies involving rare diseases or diseases that affect specific populations. There may not be enough patients in the U.S. or worldwide for a new cohort to yield statistical power for a replication study.

Data, Software, and Model Sharing (32767 characters max)

NIH must develop clearly quantifiable metrics to assess the utility and reuse of shared data, software, and models. Study section review is essential for the evaluation of these shared resources to ensure fairness amongst researchers. NIH could consider creating a “citation index” as a metric to quantify the use and reuse of shared scientific data and tools. A combination of the number of downloads, number of article citations, and number of derivative products that were developed from these resources could be used to develop the citation index.

To incentivize the development and validation of new software and models for the advancement of biomedical research, NIH should consider developing a new grant category for methodology development and *in silico* modeling development. Through this mechanism, projects that have clear plans for producing new technologies, methods, and tools could be prioritized as a way to incentivize these important activities.

Training and Mentorship (32767 characters max)

Training and mentoring graduate students and postdoctoral researchers (postdocs) is essential for the professional development of the next generation of scientists. Recognizing and rewarding effective training and mentorship will foster healthier and more productive research environments that advance medical research.

While mentorship is an essential skill for lab leaders to have, it is not routinely taught. Instead, mentorship skills are often derived from learned experiences, leaving trainee experiences to vary greatly across PIs and institutions. For mentoring to be successful, formal training in mentorship for PIs and trainees is needed to create a baseline mentoring experience to support the PI and all trainees and staff in the lab; the creation and distribution of supportive resources would further such efforts. NIH can use existing mentoring programs as a model for program development, such as the Howard Hughes Medical Institute (HHMI) Gilliam Fellows Program, which incorporates the professional development of the mentor-trainee relationship into its overall training experience. The mentor is required to go through a year-long mentorship development course to help the mentor build skills to create a healthy, supportive lab environment for their trainees’ success.

Mentorship should be viewed as a measurable competency. Evidence of effective mentorship could be collected by NIH regularly at intervals throughout the trainee's time with particular attention paid to the experiences of trainees on training grants and fellowships. To develop a measurable metric for evaluation, the mentor and mentee can create a shared training plan and conduct progress checks to track the progress and execution of the training plan. To protect trainees from potential retaliation for unfavorable evaluations, the information collected should remain confidential or should be aggregated (if there is enough aggregate information to protect anonymity). Should ineffective mentoring be identified during or after the training period, care should be taken to ensure that any consequences do not indirectly harm the trainee (e.g., negative impacts on current or future funding—whether through research project grants, training grants, fellowships, etc.— could materially harm the trainee's progress and prospects). Alternatively, a final exit survey could be conducted to gather feedback about both the mentor and mentee experience.

Quality and effective mentorship is not sufficiently recognized or rewarded through the traditional academic system. PIs do not receive adequate financial support or recognition for the time and effort required to provide excellent mentorship of graduate students and postdocs. To help shift the current academic culture, NIH should consider providing more tangible support for mentors on the K series of awards and training grants, namely providing funding and protected time, as good mentorship requires substantial time and effort. Additionally, non-monetary recognition of mentorship that can be placed on curriculum vitae (CVs) and biosketches could be modeled from NIH intramural awards from ICs such as NIA and NIMH to further showcase a PI's effectiveness in mentoring.

Collaboration (32767 characters max)

Collaboration is important for advancing research in the U.S. and around the world and is traditionally acknowledged through authorship on publications. The ordering of authors on a manuscript often fails to highlight and recognize all critical scientific contributions. NIH should develop a subsequent RFI to identify and utilize a new recognition system to better attribute collaborative efforts and credits to manuscript authors. An existing example of such a recognition system is called Contributor Roles Taxonomy (CRediT). CRediT recognizes 14 contributor roles that are designed to represent the different types of contributions that investigators make for scholarly publications. When developing metrics to assess collaborative contributions, NIH must gather additional input from the scientific community to ensure that the myriad of ways to contribute scientifically are appropriately captured.

Entrepreneurship and Translation (32767 characters max)

If entrepreneurship is to be used as a metric for measuring scientific impact, NIH should note that most scientists are not educated or trained on the topic of entrepreneurship. Educational opportunities and training will be needed to develop foundational knowledge in business development, strategy, fundraising, and technology transfer. In parallel to training, NIH could consider developing a mentoring system to partner investigators who are new to entrepreneurship with those who are experienced in entrepreneurship. NIH could incentivize entrepreneurship through the incorporation of entrepreneurial training for trainees and their mentors in training grant program curriculum.

Foundational Scientific Exploration (32767 characters max)

We identify three considerations that should be addressed to incentivize and reward foundational scientific exploration through high-risk, high-reward initiatives. First, funding for exploratory, high-risk, high-reward projects should not detract from funding for traditional research project grants. Second, training graduate students and postdocs requires additional oversight, support, and protection when working on high-risk, high-reward projects. In this regard, NIH should advise PIs to provide their trainees with a diversified project portfolio. If a high-risk, high-reward project does not work out, trainees should have other projects with less risk to support their continued scientific training. Last, when conducting high-risk, high-reward research, there is a risk that the project will not produce the anticipated results (i.e. yield negative data). Value and recognition for these worthwhile studies, regardless of the results, should be attributed to the researcher through publication or other means.

It is important to note that identifying and measuring the impact of high-risk, high-reward initiatives can be subjective. Study section review should be maintained as part of the scientific review process to evaluate and prioritize which high-risk, high-reward initiatives should be supported and to avoid penalizing investigators who took on high-risk, high-reward projects that did not yield groundbreaking results.

Public Impact (32767 characters max)

As responsible stewards of U.S. taxpayer dollars, scientists have the responsibility to share their research progress and outcomes with community members and build trust in science through public engagement. The public engagement of science is a learned skill that needs practice and refinement to maximize impact and success. Not all researchers have the opportunity to develop this skillset and put their skills to practice by speaking with non-scientists about their research.

NIH should provide workshops or other methods of science communication and public engagement training for all NIH-supported researchers. Training opportunities will make assessing and rewarding public engagement and impact more feasible and fairer. Otherwise, without such training, scientists could be unfairly penalized through the grant review process for failing to create effective public engagement plans.

The NIH should consider adopting models and practices used by agencies and organizations such as the National Science Foundation (NSF) and Patient-Centered Outcomes Research Institute (PCORI). In addition to publishing a post-study report that includes a summary for non-scientists to read, PCORI requires awardees to describe plans for the dissemination of their work beyond publications in the scientific/medical literature. NSF grant applicants are required to describe the broader impact of their work and explain how their research benefits society. NSF uses five criteria to evaluate broader impacts which includes the potential benefit to society, ability to explore transformative concepts, and feasibility. NSF does not prescribe what activities meet their broader-impacts goals, but some of their examples of desired outcomes such as increasing public scientific literacy, education, development of the STEM workforce, and increasing the economic competitiveness of the U.S. As part of the implementation process to measure public engagement and impact, the NIH should consider providing examples of meaningful engagement that will be recognized while maintaining flexibility to support novel and meaningful activities. Ideas of public engagement opportunities could include partnerships with community organizations, advocacy organizations, or science communicators, activities that specifically engage with patients or community members, or opportunities to shape policy development.

To capture, assess, and recognize researchers' efforts on the public impact of research, the NIH may need to modify the grant application to allow researchers to report their public engagement activities and outcomes. This could be done by modifying the biosketch to include a section on public engagement or by adding an additional section to the grant application itself.

Measuring and assessing the effectiveness and return on investment (ROI) as a means of quantifying scientific impact is subjective. Public impact requires both short-term and long-term monitoring and evaluation of the target audience. Additional funding and resources are needed to support short-term and long-term monitoring of proposed efforts to more accurately measure and evaluate ROI.