National Institutes of Health (NIH) Standards for Scientific Rigor and Transparency

Overview

This document provides a comprehensive framework for faculty, staff, and administrators to understand and implement NIH requirements for scientific rigor, transparency, and reproducibility in grant applications and training programs.

Defining Scientific Rigor and NIH Goals

Scientific rigor is defined as the strict application of the scientific method to ensure unbiased and well-controlled experimental design, methodology, analysis, interpretation, and reporting of results.

The NIH utilizes these standards to:

- Fund the highest quality, most rigorous science.
- Ensure applicants and reviewers consider critical details that may have been previously overlooked.
- Promote scientific integrity, public accountability, and social responsibility.
- Minimize additional administrative burden while maintaining high standards.

Applicable NIH Notices

NOT-OD-18-228: NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Research Grant Applications

NOT-OD-18-229: NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Career Development Award Applications

NOT-OD-20-033: NIH and AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for Research Training Grant, Fellowship, and Career Development Award Applications

Additional Information

For additional information, please visit: https://grants.nih.gov/faqs#/rigor-and-reproducibility.

Requirements for Research Grants and Individual Career Development Awards

Beginning in 2019, the NIH updated instructions for Research Grants and Mentored Career Development Awards to prioritize the following:

- Rigor of Prior Research: The term "scientific premise" has been replaced with "rigor of the prior research".
- Research Strategy: Applicants must use the Research Strategy section to describe plans to address any weaknesses in the rigor of prior research.
- Evaluation: Reviewers evaluate applications based on specific components addressing reproducibility, rigor, and transparency.

Checklist

☐ Evaluate the Rigor of Prior Research: Have you moved beyond the "scientific premise" to provide a detailed evaluation of the rigor of the prior research serving as the foundation for your proposal?

☐ Identify Weaknesses: Have you explicitly identified any weaknesses or gaps in the rigor of the previous research or preliminary data you are citing?

☐ Address Weaknesses in Research Strategy: Does your Research Strategy include a specific plan to address and overcome the identified weaknesses in prior research?

☐ Apply the Scientific Method: Have you described a strict application of the scientific method to ensure unbiased and well-controlled experimental designs?

☐ Transparency in Methodology: Does your proposal include sufficient detail regarding methodology, analysis, and interpretation to ensure the results are reproducible?

☐ Reporting Standards: Have you included clear plans for the reporting of results to ensure scientific integrity and public accountability?

Requirements for Training, Fellowships, and Institutional Awards

For applications submitted on or after May 25, 2020, the following mandates apply to Institutional Training Grants (T), Institutional Career Development (K series), and Individual Fellowships (F Series):

- Formal Instruction: Applications must include formal instruction in rigorous experimental design and transparency to enhance reproducibility.
- Extended Requirements: The rigor and transparency requirements previously applied only to research grants are now extended to fellowship research grants.

Checklist

☐ Formal Instruction: Does the application include a plan for formal instruction in rigorous experimental design and transparency?

☐ Enhanced Reproducibility: Is the training program structured to specifically enhance reproducibility among trainees or fellows?

☐ Fellowship Research Strategy: For fellowship research grants, have you applied the same rigor and transparency requirements used for standard research grants (see Section 1 above)?

☐ Review Criteria Alignment: Does the application address the specific components of reproducibility, rigor, and transparency that reviewers are instructed to evaluate for scientific merit?