

## Summary Report of NIH Actions Related to Rigor and Reproducibility

**Goal:** To provide the ACD Working Group with a comprehensive report of the NIH's Rigor and Reproducibility (R&R) efforts to date for consideration when developing recommendations as described in [Section 2039 of the 21<sup>st</sup> Century Cures Act](#).

**Objective 1:** Summarize the NIH's efforts in developing, implementing, and disseminating the R&R policy. To include: guide notices, RFIs, online resources, blog posts, presentations.

- Updates to research grant applications and review language
  - RFIs: [NOT-OD-14-128](#), [NOT-OD-15-020](#), [NOT-OD-17-011](#)
  - Guide notices: [NOT-OD-15-102](#), [NOT-OD-15-103](#), [NOT-OD-16-011](#), [NOT-OD-16-012](#)
  - Online resources
    - [OER Reproducibility website](#)
    - [Resource Chart](#)
    - [Infographic](#)
    - [Reviewer Guidance to Evaluating SABV](#)
  - Blog posts
    - [Scientific premise in NIH grant applications](#)
    - [Scientific rigor in NIH grant applications](#)
    - [Relevant biological variables, such as sex](#)
    - [Authentication of Key Biological and/or Chemical Resources in NIH Grant Applications](#)
  - Related RFA [PA-16-186](#)
- Reporting
  - Guide Notice [NOT-OD-16-031](#)
  - [Principles and Guidelines for Reporting Preclinical Research](#)
- Training in Rigor and Reproducibility
  - Guide Notice [NOT-OD-16-034](#)
  - Online Resources [NIGMS Clearinghouse for Training Modules](#)
  - Related RFAs: [RFA-GM-15-006](#), [PA-15-136](#), [PA-16-060](#), [PA-16-133](#), [PA-16-142](#), [PAR-17-096](#)

**Objective 2:** Describe the OER evaluation plan and provide relevant data.

- Enhancing Peer Review Phase III surveys conducted in Fall 2015
  - Surveyed five NIH stakeholders on the NIH Rigor and Reproducibility policy
    - Applicants
    - Reviewers
    - Scientific Review Officers (SROs)
    - Program Officials (POs)
    - Advisory Council Members
  - Almost 80% of respondents across all five stakeholder groups rated Scientific Premise and Rigorous Experimental Design as the two elements most relevant to their own field of science.

- There was also broad agreement among respondents that more attention to scientific rigor will improve the reproducibility of research findings in their field of science
- OER evaluation of NIH rigor and reproducibility policy
  - Qualitative Analysis: Structured Interviews with SROs and POs conducted in Summer 2016 provided several implications for NIH to consider addressing to further the policy goals
    - Encourage reviewers to provide more detail on rigor in written critiques and discussions
    - Encourage SROs to prompt timely discussion of policy elements (i.e., before scoring as appropriate).
    - Encourage review procedures that support POs' attendance at meetings
    - Provide more guidance for POs regarding post-award monitoring of rigor and reproducibility measures
  - Quantitative Analysis: Rating of grant applications and associated summary statements, expected to launch Summer 2017
    - Research questions
      - To what extent are the elements of rigor and reproducibility incorporated in grant applications?
      - Did the Rigor and Reproducibility initiative increase the extent to which applicants describe the elements of rigor in their grant applications and the extent to which reviewers consider the elements during the review process?
    - Study Design
      - Grant applications submitted before and after the launch of the policy will be assessed based on criteria developed for each of the four areas of the Rigor and Reproducibility policy
    - Development of Rating Management Systems (RMS)
      - Online interface will be used to recruit raters, assign tasks, and complete assignments
  - Internal NIH Advisory Workgroup convened to assess the evaluation strategy and provide high-level oversight for the remaining tasks

**Objective 3:** Summarize the NIH [Data Sharing policy](#).

- Note, the NIH is addressing Data Sharing as instructed in [Section 2014 of the 21<sup>st</sup> Century Cures Act](#)
- RFIs: [NOT-OD-16-133](#) and [NOT-OD-17-015](#)
- [NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources](#)
- [NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research](#)