NIH Guide Notice – Enhancing Reproducibility Through Rigor and Transparency

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Reproducibility of Research Data

- Rising concern from scientists and the general public that researchers are not doing enough to ensure the reproducibility of their research data.
- Many factors at play:
  - Training of researchers on experimental design
  - Increased emphasis on making provocative statements rather than technical details
  - Publications not reporting basic elements of experimental design (e.g., blinding, randomization, replication, sample-size calculation)

Reproducibility of Research Data

- On June 9, 2015, NIH issued a Guide Notice attempting to address these concerns.
- Guide Notice goes into effect for grant submissions after January 25, 2016.

Reproducibility of Research Data

Key features -- revised grant instructions and review criteria focusing on:

- The scientific premise of the proposed research
- Rigorous experimental design for robust and unbiased results
- Consideration of relevant biological variables
- Authentication of key biological and/or chemical resources

Reproducibility of Research Data

Scientific Premise

NIH expects proposals to focus on general strengths *and weaknesses* of the prior research being cited by the investigator in support of the application, including:

- Relevant biological variables
- Effectiveness of prior statistical analyses
- Unblinded
- Failure to discuss authentication of cell lines

Reproducibility of Research Data

Rigorous Experimental Design

NIH expects proposals to describe how they will achieve robust and unbiased results. This includes full transparency in reporting experimental details so that others may reproduce and possibly extend research findings.

Reproducibility of Research Data

Consideration of Sex and Other Biological Variables

- Sex of the subject is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences.
- NIH expects proposals to take sex into account as a biological variable and be factored into research designs, analyses, and reporting.
- Proposals to only study one sex must be supported by strong justification from the scientific literature.

Reproducibility of Research Data

Authentication of Key Biological and/or Chemical Resources

- NIH expects that key biological and/or chemical resources will be regularly authenticated.
- NIH is enlisting the research community to develop guidelines that will more explicitly describe the expectations, but researchers still required to report on what they have done to authenticate key resources.