RIGOR AND REPRODUCIBILITY

Rigor and Reproducibility

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Updated Application Instructions to Enhance Rigor and Reproducibility

The National Institutes of Health (NIH) Office of Extramural Research (OER) clarified and revised application instructions and review criteria to enhance reproducibility of research findings through increased scientific rigor and transparency. These updates took effect for research grants and mentored career development award applications submitted for the January 25, 2016 due date and beyond. Updates to institutional training grants, institutional career development awards (K12/KL2), and individual fellowships will be forthcoming in 2017 or later.

Newly revised grant application instructions clarify long-standing expectations to ensure that NIH is funding the best and most rigorous science, highlight the need for applicants to describe details that may have been previously overlooked, highlight the need for reviewers to consider such details in their reviews through revised review criteria, and minimize additional burden. These new instructions and revised review criteria focus on four areas deemed important for enhancing rigor and transparency:

Scientific Premise of Proposed Research

Rigorous Experimental Design

Scientific rigor is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. This includes full transparency in reporting experimental details so that others may reproduce and extend the findings. NIH expects applicants to describe how they will achieve robust and unbiased results when describing the experimental design and proposed methods. Robust results are obtained using methods designed to avoid bias and can be reproduced under well-controlled and reported experimental conditions.

Consideration of Sex and Other Relevant Biological Variables

Authentication of Key Biological and/or Chemical Resources

Investigators are strongly encouraged to discuss these revised application instructions with NIH program staff prior to submission of applications. Further information is provided at the following website: http://grants.nih.gov/reproducibility/index.htm

This page last reviewed on April 28, 2016

NEW GRANT GUIDELINES

what you need to know

WHY UPDATE THE GUIDELINES?

The updates focus on four areas deemed important for enhancing rigor and transparency:

1 PREMISE
The scientific premise forming the basis of the proposed research

2 DESIGN
Rigorous experimental design for robust and unbiased results

3 VARIABLES
Consideration of relevant biological variables

4 AUTHENTICATION
Authentication of key biological and/or chemical resources

Send inquiries to reproducibility@nih.gov

See also NIH Notice NOT-OD-16-011
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html

WHAT ARE THE UPDATES?

1 UPDATES TO RESEARCH STRATEGY GUIDANCE

The research strategy is where you discuss the significance, innovation, and approach of your research plan. Let's look at an R01, for example:

The new **research strategy** guidelines require that you:

- State the strengths and weakness of published research or preliminary data crucial to the support of your application
- Describe how your experimental design and methods will achieve robust and unbiased results
- Explain how biological variables, such as sex, are factored into research design and provide justification if only one sex is used

2 NEW ATTACHMENT FOR AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

From now on, you must briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

These include, but are not limited to:

CELL LINES
ANTIBODIES
SPECIALTY CHEMICALS
OTHER BIOLOGICS

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

☒ **DO NOT** put experimental methods or preliminary data in this section

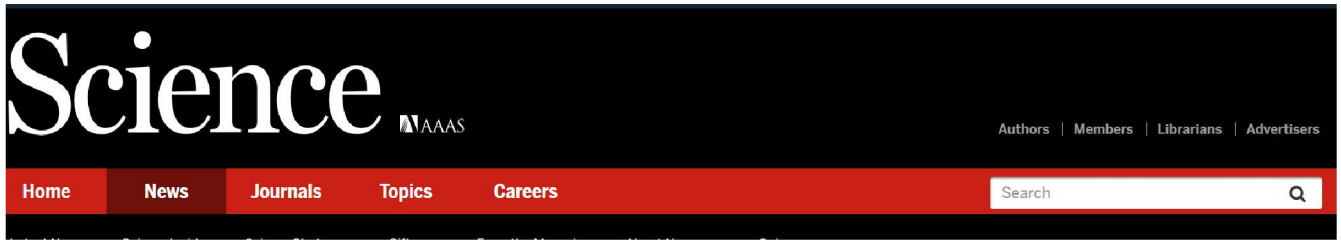
☑ **DO** focus on authentication and validation of key resources

3 NEW REVIEWER GUIDELINES

Here are the additional criteria the reviewers will be asked to use:

- Is there a **strong scientific premise** for the project?
  - Have the investigators presented adequate plans to address **relevant biological variables**, such as sex, for studies in vertebrate animals or human subjects?
    - Have the investigators presented strategies to ensure a **robust and unbiased approach**, as appropriate for the work proposed?

Reviewers will also be asked to comment on that new attachment (see Update 2)!



NIH aims to beef up clinical trial design as part of new data sharing rules

By Jocelyn Kaiser | Sep. 16, 2016 , 12:00 PM

Drug companies and academic researchers will have to step up their public reporting of clinical trial results under new federal policies released today. The National Institutes of Health (NIH) in Bethesda, Maryland, also laid out a new plan for submitting clinical trial proposals that aims to beef up the rigor of the studies.

Researchers can no longer submit an unsolicited idea, but must respond to a request for applications that will include specific design requirements. The goal is to cut down on the number of "small crappy studies," that don't include sufficient numbers of patients or veer off from the original study plan, NIH staffers say. The agency wants to "reengineer the process by which clinical investigators develop ideas for new trials," NIH officials explain in a **commentary today in *The Journal of the American Medical Association*** (*JAMA*).

Shortlisted for the BBC Samuel Johnson Prize for Non-Fiction

Bad Science

Ben Goldacre

'A fine lesson in how to skewer the enemies of reason and the peddlers of cant and half-truths' The Economist

'You'll laugh your head off, then throw all those expensive health foods in the bin' Observer, Book of the Year

Half a million copies sold worldwide

A Rough Guide to

SPOTTING BAD SCIENCE

Being able to evaluate the evidence behind a scientific claim is important. Being able to recognise bad science reporting, or faults in scientific studies, is equally important. These 12 points will help you separate the science from the pseudoscience.

1. SENSATIONALISED HEADLINES

Article headlines are commonly designed to entice viewers into clicking on and reading the article. At times, they can over-simplify the findings of scientific research. At worst, they sensationalise and misrepresent them.

2. MISINTERPRETED RESULTS

News articles can distort or misinterpret the findings of research for the sake of a good story, whether intentionally or otherwise. If possible, try to read the original research, rather than relying on the article based on it for information.

3. CONFLICTS OF INTEREST

Many companies will employ scientists to carry out and publish research - whilst this doesn't necessarily invalidate the research, it should be analysed with this in mind. Research can also be misrepresented for personal or financial gain.

4. CORRELATION & CAUSATION

Be wary of any confusion of correlation and causation. A correlation between variables doesn't always mean one causes the other. Global warming increased since the 1800s, and pirate numbers decreased, but lack of pirates doesn't cause global warming.

5. UNSUPPORTED CONCLUSIONS

Speculation can often help to drive science forward. However, studies should be clear on the facts their study proves, and which conclusions are as yet unsupported ones. A statement framed by speculative language may require further evidence to confirm.

6. PROBLEMS WITH SAMPLE SIZE

In trials, the smaller a sample size, the lower the confidence in the results from that sample. Conclusions drawn can still be valid, and in some cases small samples are unavoidable, but larger samples often give more representative results.

7. UNREPRESENTATIVE SAMPLES USED

In human trials, subjects are selected that are representative of a larger population. If the sample is different from the population as a whole, then the conclusions from the trial may be biased towards a particular outcome.

8. NO CONTROL GROUP USED

In clinical trials, results from test subjects should be compared to a 'control group' not given the substance being tested. Groups should also be allocated randomly. In general experiments, a control test should be used where all variables are controlled.

9. NO BLIND TESTING USED

To try and prevent bias, subjects should not know if they are in the test or the control group. In 'double blind' testing, even researchers don't know which group subjects are in until after testing. Note, blind testing isn't always feasible, or ethical.

10. SELECTIVE REPORTING OF DATA

Also known as 'cherry picking', this involves selecting data from results which supports the conclusion of the research, whilst ignoring those that do not. If a research paper draws conclusions from a selection of its results, not all, it may be guilty of this.

11. UNREPLICABLE RESULTS

Results should be replicable by independent research, and tested over a wide range of conditions (where possible) to ensure they are consistent. Extraordinary claims require extraordinary evidence - that is, much more than one independent study!

12. NON-PEER REVIEWED MATERIAL

Peer review is an important part of the scientific process. Other scientists appraise and critique studies, before publication in a journal. Research that has not gone through this process is not as reputable, and may be flawed.