



Statistical Issues Seen in Non-Statistics Proposals

A Guide to Improving the Science in Non-Statistics Proposals for Funding
from the American Statistical Association Committee on Funded Research¹

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As the science of learning from data, and of measuring, controlling, and communicating uncertainty,² statistics can help to improve science at all stages, beginning with framing and design issues. One indication of the scientific influence of statistics is that, in a 2014 Nature article on the 100 most cited research articles ever³, [nine were by statisticians and two more were largely statistical](#).

To assist researchers of all disciplines in improving their scientific work, the ASA Committee on Funded Research reached out to ASA membership in August 2016 for input on what statistical issues they see in non-statistics grant proposals. In order to help grant applicants strengthen their proposals and lead to better science, the committee has prepared this document. The document starts with a listing of the primary statistical issues identified in non-statistics proposals for funding followed by recommendations for applicants, funding agencies, and statisticians. After a call-for-comment period in October 2016, they revised the document resulting in this final version.

The June 2016 PLOS article from, "[Ten Simple Rules for Effective Statistical Practice](#),"⁴ and the September 2016 *Peer Review Notes* article, "[Statisticians Share Insights for Applicants and Reviewers](#)"⁵ (which inspired this document), may also be helpful to readers.

¹ The specific authors from the committee are: Ming-Wen An (committee chair), William Christiansen (vice-chair), Debashis Ghosh, Sujit Ghosh, Scott Holan, Leslie McClure, Karen Messer, and Cynthia Rudin. The committee also thanks the many who contributed to the document, particularly Andrew Althouse. The staff contacts are ASA Director of Science Policy Steve Pierson (pierson@amstat.org) and ASA Director of Strategic Initiatives and Outreach Donna LaLonde (DonnaL@amstat.org).

² Davidian M, Louis TA (2012), Why Statistics? Science 336 p. 12. doi: 10.1126/science.1218685
<http://science.sciencemag.org/content/336/6077/12>

³ Van Noorden R, Maher B, Nuzzo R (2014) The Top 100 Papers. Nature 514 p. 550 <http://www.nature.com/news/the-top-100-papers-1.16224>

⁴ Kass RE, Caffo BS, Davidian M, Meng X-L, Yu B, Reid N (2016) Ten Simple Rules for Effective Statistical Practice. PLoS Comput Biol 12(6): e1004961. doi:10.1371/journal.pcbi.1004961.
<http://journals.plos.org/ploscompbiol/article?id=10.1371/journal.pcbi.1004961>

Statistical Issues:

1. Framing the Problem:
 - a. Are all of the study's objectives (e.g., specific hypotheses to be tested) clearly defined? What is the scientific question of interest - inference about a treatment effect, estimation, prediction, etc.?
 - b. For experiments or sampling-based observational studies, what is the population in mind? For studies focused on estimation and prediction in other settings, what is the end purpose of the proposed statistical modeling (e.g., "estimating historical temperature changes over time" or "predicting future changes")?
 - c. What assumptions are being made about the data being collected? How do these assumptions relate to the estimation procedure and the population inference?
2. Designing the Study/Experiment:
 - a. Are the proposed data appropriate for addressing the study's objectives? Are the proposed data described in sufficient detail? Are the study variables identified as outcomes, predictors, or potential confounders?
 - b. Are proposed sample sizes sufficient to support adequate power, precision of confidence intervals, or minimal prediction error? Are calculations well-documented and reproducible (e.g., to reproduce a power analysis)? Have adjustments for multiple comparisons or multiple inferences been considered?
3. Specifying the Data Analysis Plan:
 - a. Is the proposed analysis method the most appropriate for the research question?
 - b. Has the statistical analysis method associated with each component of the research been carefully described?
 - c. Is the approach robust? How will missing data be handled?
 - d. What approach will be taken for multiple comparisons or multiple inferences? (If none, then carefully justify).
 - e. What approach will be taken for sensitivity analysis and/or external validation?

Recommendations:

1. Recommendations for non-statistician PI's:
 - a. Partner with a statistician in the design and planning phases of the study. Specifically, in addition to the data analysis and report writing, the statistician can lend expertise in framing the precise question to be answered, delineating the scope and nature of the study, ensuring that data are collected completely, and monitoring the progress of the study. Studies requiring sophisticated analyses may be open to criticism if statisticians are absent. This is particularly true when the study involves one or more complicating factors including massive data sets, missing observations, causal modeling, Bayesian modeling, uncertainty propagation, multiple testing issues, more predictor variables than observations, hierarchical models, measurement error, or spatial/temporal modeling.

⁵ Statisticians Share Insights for Applicants and Reviewers, Peer Review Notes, September, 2016, <https://www.csr.nih.gov/CSRPRP/2016/09/statisticians-share-insights-for-applicants-and-reviewers/>.

- b. Work with your statistical collaborator to ensure sufficient effort is budgeted to complete the proposed work. Insufficient funding for a statistician does not allow for statistical support for unexpected study issues, including approaches to drop-outs, missing data, or treatment contamination. Further, providing sufficient support for your statistical collaborator signals to the funding agency that the collaborative group understands the importance of statistical modeling and analysis to their success.
 - c. Your institution's statistics or biostatistics departments may have guidance for estimating statistician or biostatistician effort. See, for example, [University of California Davis School of Medicine Guidelines for Estimating Biostatistician Effort and Resources on Grants](#).
 - d. Consider including an appendix with annotated and reproducible code to support design and power considerations.
2. Recommendations for funding agencies:
- a. Standing review panels should include one or more permanent members who are statisticians with expertise and credentials in the subject matter domain of the particular panel. This would be an effective way for statistical thinking and considerations to become imbedded in the thinking of the review panel and to help shape the reviews in the long run.
 - b. Ad hoc and special emphasis review panels should also include statisticians. It is worth noting that a revolving membership will make it a challenge to develop a consistent and well thought out approach to research in the domain of the panel and the corresponding statistical perspective.
3. Recommendations for biostatisticians and statisticians:
- a. Strive to be a scientific collaborator (versus a statistical consultant) in research activities: (i) learn the subject matter; (ii) be actively involved in developing the research questions; (iii) participate in the top subject-area conferences; (iv) collaborate on manuscripts in the subject area; etc.
 - b. For statisticians to be effective in review panels, they need to be received as bona fide researchers in the interdisciplinary space and not as narrow technicians. Such a reception on a review panel is greatly helped by expertise within the scientific area via formal training, collaborative research experiences, and other activity within the scientific community.
 - c. Request guidance on how to be successful/effective members of a study section or review panel from experienced colleagues and the ASA .
4. Recommendations for biostatistical/statistical departments and/or units:
- a. Departments should recognize and value the importance of serving on subject-matter grant review panels.
 - b. Departments should continue to develop resources for estimating statistician or biostatistician effort, like the previously cited example from the UC Davis Biostatistics Department. Such guidelines should apply to all funding levels and most grant types, not just larger grants.