New NIH Guidelines on Sex Inclusion, Rigor, and Transparency
Provided by Jody Hirsch, Chemistry of Life Processes Institute

Beginning after January 25, 2016, there will be changes in NIH proposal language regarding sex-inclusion, rigor, and transparency. The following is a summary of the most relevant changes:

1. **NOT-OD-16-011: Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications.**
   Updates to review of significance and research strategy in four areas:
   1) The scientific premise forming the basis of the proposed research,
   2) Rigorous experimental design for robust and unbiased results,
   3) Consideration of relevant biological variables including enforcement of the requirement to consider sex as biological variable (NOT-OD-15-102). Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
   4) Authentication of key biological and/or chemical resources. New required attachment: “Authentication of Key Biological and/or Chemical Resources” There are no standard formatting guidelines yet for this section, since it is new and applies to a wide variety of resource types. For more info you can also see: [http://grants.nih.gov/reproducibility/index.htm](http://grants.nih.gov/reproducibility/index.htm)
   FAQs: [http://grants.nih.gov/reproducibility/faqs.htm](http://grants.nih.gov/reproducibility/faqs.htm)

2. **NOT-OD-16-006: Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals Summary of Changes**
   - A description of veterinary care is no longer required.
   - Justification for the number of animals has been eliminated.
   - A description of the method of euthanasia is required only if the method is not consistent with AVMA guidelines.

3. **Biosketch Clarifications**
   - A URL for a publication list is optional and, if provided, must be to a government website (.gov) like “My Bibliography”
   - Explicitly states that graphics, figures and tables are not allowed

4. **For applications due 5/25/16 and after:** A new form will partially replace the cover letter to indicate:
   - PHS Awarding Component (including NIH Institute/Center (IC) Requests), both positive (“assign to”) and negative (“do not assign to”)
   - Study Section or Special Emphasis Panel Requests, both positive and negative
   - List of potential reviewers in conflict, and why
   - List of scientific expertise needed to review the application

*The cover letter will still be used in cases where you need to communicate other issues to CSR, e.g. reason for late submission.*

http://www.womenshealth.northwestern.edu