**NIH grant changes effective for grants due on or after January 25th, 2016**

For research grant applications due on or after **January 25th, 2016**, the NIH has new guidelines focused on improving **scientific rigor, reproducibility, and transparency (NOT-OD-16-011/NOT-OD-16-012)**. Research grants include most R series, P series, and U series grants.

* **In the Significance section of the research plan; within the current page limits**
  + Describe the scientific premise for the proposed project
    - Include consideration of the strengths and weakness of published research and preliminary data crucial to your application
    - May include previous experimental design, authentication of key resources, incorporation of relevant biological variables
    - Contributes to criterion and impact scores of the application; Reviewers will be asked “Is there a strong scientific premise for the project?”
* **In the Approach section of the research plan; within the current page limits**
  + Describe the experimental design and methods proposed and how they will achieve a robust and unbiased result
    - Includes robust and unbiased experimental design; transparency in research reporting
    - Likely to include discussion/justification of animal numbers
    - Contributes to criterion and impact scores of the application; Reviewers will be asked “have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”
  + Explain how relevant biological variables, especially sex, are factored into research designs for vertebrate animals and humans
    - If only using one sex, must include strong justification from scientific literature and/or preliminary data
    - Contributes to criterion and impact scores of the application; Reviewers will be asked “Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects”
* **In a separate attachment, not included in the research plan; can be no more than 1 page in length, which does NOT count towards the current page limits**
  + Authentication of Key Biological and/or Chemical Resources
    - Describe methods to ensure the identity and validity of key resources used in the proposed studies
    - Each researcher must determine for themselves which resources in their proposed studies fit as key.
    - Criteria:
      * Have potential to differ from one laboratory to the next over time
      * Have qualities that could influence research data
      * Are integral to the proposed research
      * Are NOT limited to resources generated with NIH funds
    - May include, but are not limited to cell lines, antibodies, specialty chemicals
    - **Do NOT include other methods/preliminary data in this section or application will be withdrawn!!**
    - Reviewers comment on the proposed plan but it **does not count in the overall impact score**; however, questions will need to be addressed prior to award
    - Until May 25, 2016**, upload attachment titled “Authentication of Key Resources Plan” in the “Other Attachments” section of the “Other Project Information” form.**
* Other changes
  + Vertebrate animals section has been simplified to remove redundancy with IACUC
    - No description of veterinary care required
    - No justification for number of animals required (should be addressed in research strategy section)
    - No description/justification of euthanasia method if method is consistent with AVMA guidelines
  + Definition of a child: under 18 years old (used to be under 21 years old)
  + Research Performance Progress Reports (submitted on or after January 25, 2016)
    - Expected to emphasize rigorous approaches taken to ensure robust and unbiased results
    - Rigor should be addressed on progress reports for any grant that funds research or training in research (i.e. not shared instrumentation grants, etc.)
    - These requirements do apply to non-competing continuations for grants awarded before this policy
  + Some changes in research training:
    - Recruitment and Retention Plan to Enhance Diversity – focus on recruitment
    - Human Subjects – describe how you will ensure that trainees only participate in exempt human subjects research or non-exempt that has IRB approval; do NOT need to provide a list of potential grants trainees may work on
    - Vertebrate animals – describe how institution will ensure that trainees only participate in IACUC approved research; do NOT need to provide list of potential grants
    - Progress Report – report on publications in the Just-in-Time process