**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