OSRA Updates
NIH Grants Policy Statement and SF424 Application Guide

On November 25th the National Institutes of Health issued a new Grants Policy Statement (GPS) and SF424 Application Guide. The following highlights outline updates directly relevant to the grant submission and management process. We urge all faculty and administrative staff to review the below carefully.


➢ SF424 Guide – Major Highlights

1. The new guide is applicable for NIH due dates on and between January 25, 2016 and May 24, 2016.

2. The Significance and Approach sections of the Research Strategy have many new requirements focusing on rigor and transparency. See sections 5.5 PHS 398 Research Plan Form pages I-133 to I-136

New language:
   a. **Significance**: Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
   b. **Approach**:
      i. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
      ii. 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.
      iii. If your study involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample.

3. Updated **Vertebrate Animals Section** instructions. See section 5.5 PHS 398 Research Plan Form pages I-137 to I-138
4. **Genomic Data Sharing** requirements: Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data in the Resource Sharing Plan section of the funding application. See section 5.5 PHS 398 Research Plan Form pages I-142 to I-143. Application cover letters should contain a statement if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy.

5. Other Attachments Section should now include **Authentication of Key Biological and/or Chemical Resources** document, when applicable. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.
   a. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
   b. 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.

6. The supplemental instructions for Fellowship (F) applications is new as there is no longer a separate guide for this mechanism.

➢ **Grants Policy Statement – Major Highlights**

NIH’s summary of GPS changes table can be found here: http://grants.nih.gov/grants/policy/nihgps/Significant_Changes_NIHGPS_Oct2015.pdf, the below expands upon items of most interest to faculty and administrators but is not all inclusive. The full Statement can be found here: http://grants.nih.gov/grants/policy/nihgps/index.htm

1. **Effort Reduction during the EWOF period**
   a. **Section 8.1.3 EWOF** policy now states “With the exception of grant programs that have an effort requirement, or where terms and conditions prohibit such reductions, NIH will not require prior approval for the reduction in effort for Senior/Key personnel. The recipient is reminded that active awards must have a measurable level of effort.”
   b. Given that the new GPS applies to awards issued with a budget period start date on or after 10/1/2015, this new rule does not apply to grants currently in an EWOF period or any grant with a budget period start date prior to 10/1/2015 that may go into an EWOF period. In those instances, NIH prior approval is still required, but only for key personnel listed in the NOA that reduce their effort by 25% or more.

2. **Genomic Data Sharing**
   a. **Section 2.3.7.10** mandates that applications proposing to generate large-scale human and/or non-human genomic data are expected to include a genomic data sharing plan.
   b. This Section also requires that applicants who wish to use controlled-access human genomic data from NIH-designated data repositories briefly address their plans for
requesting access to the data in the application and state their intention to abide by the NIH Genomic Data User Code of Conduct.

3. Non-compliance Reminder
   a. **Section 2.3.9.5 Application Non-compliance** reminds applicants that NIH may withdraw any application identified during the receipt, referral and review process that is not compliant with the instructions in the SF424 (R&R) Application Guide, the Funding Opportunity Announcement, and relevant NIH Guide Notices.

4. **Section 8.1.2.5** expands NIH prior approval requirements in two areas related to human subjects research
   a. Delayed onset human subjects research – following award, once plans for research involving humans subjects are formed and an awardee can prepare a detailed human subjects section, this must be submitted to NIH for approval prior to commencing human subjects research.
   b. Changes to human subjects research requires prior NIH approval, including:
      i. An addition or change to the study design/protocol that would result in the need to change the overall human subjects designation or clinical trial designation of the grant:
         1. From non-human subjects research to human subjects research (exempt or non-exempt);
         2. From exempt to non-exempt human subjects research; or
         3. From “No Clinical Trial” to “Includes a Clinical Trial”; see revised NIH definition of clinical trial
      ii. The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR 46 subparts B, C or D (pregnant women, human fetuses, and neonates; prisoners; or children).
      iii. Any change to the study protocol that would result in an overall increase in risk level for subjects.
      iv. New information that comes to light after a study is underway which indicates a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.

**New NIH Data Tables – Major Highlights**

1. For RPPRs due on or after December, 1, 2015 and applications using the SF424 (R&R) submitted on or after May 25, 2016, new training table formats must be used.


3. Reducing the maximum number of tables from 12 to 8
   a. Tables 9 – 12 are eliminated, removing or relocating information collected on Qualifications, Admissions and Completion Records, and Appointments Data

4. Minimizing the reporting of individual-level information
a. Table 5A & 5B no longer contain prior academic degree information including institution, degree type and degree year

5. Extending the tracking of trainee outcomes from 10 to 15 years
   a. New table formats permit an evaluation of the effectiveness in achieving the training objectives for up to 15 years

➢ **RPPR Submission Guide – last updated November 3\(^{rd}\) 2015**

The guide does not yet address rigor and transparency requirements. NIH notice NOT-OD-16-011 states that the guide will be updated by January 25\(^{th}\), 2016.