Summary of the NIH/AHRQ Changes to Policies, Instructions and Forms starting 2016
(Applicable to most research grants; some mechanisms are added in phase 2 or are excluded)

Please find the full announcement in this link:

The SF424 Guidelines have been updated with these changes (Nov 25th, 2015):

PHASE 1: Between January 25th – May 25th 2016 (current FORMS-C are still in use)

A. Rigor and Transparency in Research - to enhance reproducibility of research findings through increased scientific rigor and transparency. NOT-OD-16-011

  1. Changes to the Research Strategy:

     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.

     Approach
     Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. 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. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

  2. A new "Authentication of Key Biological and/or Chemical Resources" attachment:

     Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

     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.

     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.

     Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy.

  3. On progress reports (RPPR): NOT-OD-16-031

     Additional guidance for 6.2 Section B – Accomplishments:
     B.2 What was accomplished under these goals? - Include the approaches taken to ensure robust and unbiased results.
     B.6 What do you plan to do for the next reporting period to accomplish these goals? - Discuss efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased.

B. Vertebrate Animals NOT-OD-16-006

- A description of veterinary care is no longer required
- Justification for the number of animals has been eliminated (which means that power analysis or any other statistical considerations related to the number of animals should be included in the Research Plan, not here)
- A description and justification of the method of euthanasia is required only if the method is not consistent with AVMA Guidelines for the Euthanasia of Animals
- All the other requirements are still in place (description of procedures, justification of animal use, minimization of pain, euthanasia).

C. Definition of Child  NOT-OD-16-010
- The age of a child will be defined as individuals under 18 years old (instead of under 21 years old)

D. Research Training Program Plan (for T32 Training grants)
- "Recruitment and Retention Plan to Enhance Diversity" - applicants will be asked to focus on recruitment
- "Human Subjects" - applicants must describe how the institution will ensure that trainees only participate in exempt human subjects research or non-exempt human subjects research that has IRB approval; no longer necessary to provide a list of potential grants trainees may work on and associated IRB information
- "Vertebrate Animals" - applicants must describe how the institution will ensure that trainees only participate in vertebrate animal research that has IACUC approval; no longer necessary to provide a list of potential grants trainees may work on and associated IACUC information
- "Progress Report" - requirement to report on publications that arose from work conducted by the trainee while supported by the training grant will be moved to the Just-in-Time process

E. Biosketch Clarifications
- An URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography
- Publications (peer-reviewed and non-peer-reviewed) and research products may be cited in both the personal statement and the contributions to science sections
- Graphics, figures and tables are not allowed
- An updated biosketch form with a new expiration date (10/31/2018) has been published (no other changes from the 5-page format). See link: https://grants.nih.gov/grants/funding/424/SF424R_biosketch_VerC.docx

**PHASE 2: After May 25th 2016 (when the new FORMS-D will be used)**

In addition to changes in Phase 1:

F. Inclusion Forms
- A new optional PHS Inclusion Enrollment Report form will be added to FORMS-D application packages
- The new form, with additional study descriptors, will replace the optional Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms found in FORMS-C application packages.

G. Data Safety Monitoring
- A new, separate, “Data Safety Monitoring Plan” will be added to the following forms in FORMS-D application packages:
  - Research Plan
  - Career Development Supplemental Form (for Fellowships)
  - Fellowship Supplemental Form
  - Research Training Program Plan (for T32 applications)
- This new attachment must be included with all applications involving clinical trials.
- Although the requirement of a data and safety monitoring plan for clinical trials is not new, the use of a separate attachment to collect this information will emphasize its importance and facilitate systematic enforcement of its presence.

H. Research Training Program Plan (for T32 Training grants and some RPPRs)  NOT-OD-16-007
- Reducing the number of tables from 12 to 8
- Minimizing the reporting of individual-level information
- Extending the tracking of trainee outcomes from 10 to 15 years
- NIH’s xTRACT system to help applicants prepare the new tables will be available October 16, 2015.
I. Appendices – a new policy is under review, to be released in Spring 2016.

J. New Assignment Request Form [NOT-OD-16-008]
- An optional form will be added to FORMS-D to address:
  - Awarding component (NIH institute) assignment preference
  - Study Section preference
  - List of potential reviewers in conflict, and why
  - List of scientific expertise needed to review the application

K. New Font Guidelines [NOT-OD-16-009]
- Additional fonts are allowed, as long as they comply with specific type density and line spacing guidelines.
  - **Font size**: must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)
  - **Type density**: must be no more than 15 characters per linear inch (including characters and spaces)
  - **Line spacing**: must be no more than six lines per vertical inch
  - **Text Color**: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable as long as it is legible)

- Since some PDF converters may reduce font size, it is important to confirm that the final PDF document complies with the font requirements.
- The following fonts are recommended, although other fonts (both serif and non-serif) are acceptable if they meet the requirements.
  - Arial
  - Garamond
  - Georgia
  - Helvetica
  - Palatino Linotype
  - Times New Roman
  - Verdana