

2016 NIH Update

Presented by

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THE UNIVERSITY OF
TENNESSEE
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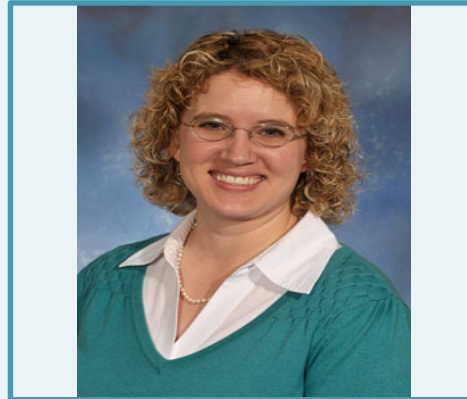
OFFICE OF RESEARCH &
ENGAGEMENT

PRESENTERS



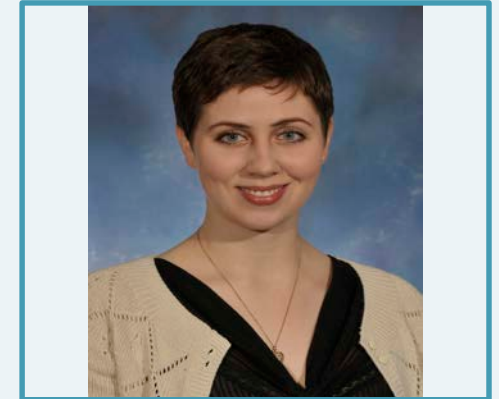
Stephanie Smith

**Post-Award
Office of Sponsored Programs**



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**NIH Liaison
Research Development Team**

PRE-AWARD UPDATES

APPLICATION COMPLIANCE

Reminder: NIH Policy on Application Compliance

“... To be fair to all concerned, NIH needs to consistently apply standards for application compliance. Be mindful that non-compliance can have serious consequences. NIH may withdraw any application ... that is not compliant with the instructions.”

Notice N

Key Date

Release Date: /

Related /

None

Issued by

National Institut

Purpose

The purpose of compliance.

Policy

Be mindful that instructions in the

Some examples

- Application
- Application (080).
- Application (059).
- Application

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It is important to remember that these are just examples, and that all requirements specified in the SF424 (R&R) Application Guide, the Funding Opportunity Announcement, and relevant NIH Guide Notices are to be followed. When in doubt about compliance policy, contact NIH "Grants Info" or the Division of Receipt and Referral as listed below.

If an application is withdrawn because it does not conform to the application preparation and submission instructions, a letter will be placed in the eRA Commons Status page for that application. The PD/PI and the AOR from the applicant organization will be notified by eRA Commons to access their account and view the explanatory letter.

SUBMITTING YOUR APPLICATION

- **Cayuse 424 launch planned for Spring 2016**
 - **Once available, ORE recommends using this system-to-system submission mechanism**
- **ASSIST now available for all applications**
- **Grants.gov forms**
 - **Use FORMS-C for due dates 01/25/16 – 05/24/16**
 - **Use FORMS-D for due dates on or after 05/25/16**
 - **Now support full Unicode character set**

TRANSITION TO NEW REQUIREMENTS

- **Phase 1: Due dates 01/25/16 – 05/24/16**
 - Use Grants.gov FORMS-C
 - Use [SF424 Application Guide](#) issued 11/25/15
- **Phase 2: Due dates on or after 05/25/16**
 - Use Grants.gov FORMS-D
 - NIH will release an updated SF424 Application Guide by 03/25/16
- Full details available at [NIH-OD-16-004](#)

TRANSITION TO NEW REQUIREMENTS

REQUIREMENT	PHASE 1	PHASE 2
SF424 Application Guide	Released 11/25/15	Released 03/25/16
Grants.gov Forms	FORMS-C	FORMS-D
Updated Peer Review Criteria (Research Grants)	In Use	In Use
Updated Research Strategy (Research Grants)	In Use	In Use
New Authentication of Key Biological and/or Chemical Resources Document (Research Grants)	In Use	In Use
New Assignment Request Form	N/A	In Use
Updated Vertebrate Animal Guidelines	In Use	In Use
Updated Definition of Child	In Use	In Use
Updated Inclusion Forms	N/A	In Use
Updated Research Training Data Tables	N/A	In Use
Updated Research Training Program Plan	In Use	In Use
New Data Safety Monitoring Plan Document	N/A	In Use
Revised Appendix Policy	N/A	In Use
New Font Guidelines	N/A	In Use

RIGOR AND TRANSPARENCY

Study claims \$28 billion a year spent on irreproducible biomedical research

Tweet Share 76



Jocelyn is a staff writer for *Science* magazine.

Email Jocelyn

to stimulate discuss
promote some solu
Freedman, presiden
Washington, D.C.,

“There has been a confluence of concern from various sources within the scientific community and from outside the scientific community in the last few years that **the scientific enterprise is not producing new knowledge of sufficiently high quality ... This issue of reproducibility is a problem of increasingly great concern to the scientific community itself and it is, one could argue, legitimately of interest to the broader society because of the robust public support of scientific research.**” –AAAS Forum

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ng; we trust that, even
ntually be discovered
findings. However, as
Director Larry Tabak,

A growing chorus of concern, from scientists and laypeople, contends that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring.”

RIGOR AND TRANSPARENCY

- **Affects four key areas:**
 - Scientific premise
 - Rigorous experimental design
 - Consideration of relevant biological variables
 - Authentication of key biological and/or chemical resources

PEER REVIEW CRITERIA

- **Significance**
 - Is there a strong **scientific premise** for the project?
- **Approach**
 - Have the investigators presented strategies to ensure a **robust and unbiased approach**, as appropriate for the work proposed?
 - Have the investigators presented adequate plans to address relevant **biological variables**, such as sex, for studies in vertebrate animals or human subjects?
- For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources

RESEARCH STRATEGY

- **Significance**
 - Describe the **scientific premise** for the proposed project, including consideration of the strengths and weaknesses of published research or crucial preliminary data
- **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 (if not, explain why)

SCIENTIFIC PREMISE

- **Discuss strengths and weakness of the data and previously performed work**
- **Weaknesses in scientific rigor or gaps in transparency should be acknowledged**
- **If weaknesses are identified...**
 - **Reconsider its inclusion in support of the application**
 - **Describe how the proposed research will address the weaknesses**

EXPERIMENTAL DESIGN

- **Emphasize how the experimental design and methods proposed will achieve robust and unbiased results capable of being reproduced**
 - **Include use of appropriate statistical methods, prospective sample size estimation, replicates, or standards**
 - **Robust and credible results are those obtained with methods specifically designed to avoid bias, such as blinding, randomization, and prospectively defined exclusion/inclusion criteria**
- **Provide enough detail to assure reviewers that the necessary elements of rigor will be addressed**

BIOLOGICAL VARIABLES

- **If biological variables are known to affect a system or disease model, discuss how you will control these factors (if necessary)**
- **Variables include (but are not limited to)...**
 - **Human: Sex, age, BMI, socioeconomic status, underlying health conditions**
 - **Animal: Strains, vendor, housing conditions**

AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

- 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
 - May differ from laboratory to laboratory or over time
 - May have qualities and/or qualifications that could influence the research data
 - Are integral to the proposed research
 - Include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics

AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

- Standard laboratory reagents that are not expected to vary (for example, buffers and other common biologicals or chemicals) do not need to be included**
- 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**

RESOURCE AUTHENTICATION

- Do not provide authentication data itself
- Explain *how* you will authenticate key resources, and how often
- Resources requiring authentication will vary
- Describe plans to independently authenticate even vendor verified resources
- Methods will vary by resource and field

RIGOR AND TRANSPARENCY

- Takes effect 01/25/16 for Research Grants (R)
 - Numerous exceptions detailed in official notices
 - Check final FOA to ensure new guidelines apply
- Implementation delayed to 2017 for Institutional Training Grants (T), Career Development Awards (K), and Individual Fellowships (F)
- See [NOT-OD-16-004](#), [NOT-OD-16-011](#), [NOT-OD-16-012](#), and [NOT-OD-16-034](#)

ASSIGNMENT REQUEST FORM

- ORE strongly recommends using this form
- Replaces the Cover Letter attachment to provide application referral information, including:
 - Institute/Center preference
 - Study Section preference
 - List of potential reviewers in conflict, and why
 - List of scientific expertise needed for review
- The Cover Letter attachment may still be used to communicate a variety of other issues
- Takes effect 05/25/16
- See [NOT-OD-16-008](#)

VERTEBRATE ANIMAL GUIDELINES

- Criteria to be addressed have been updated
- Summary of changes:
 - Description of veterinary care no longer required
 - Justification for number of animals eliminated
 - Description of method of euthanasia required only if not consistent with AVMA guidelines
- Takes effect 01/25/16 for most applications
- Takes effect 05/25/16 for F and T series
- See [NOT-OD-16-006](#)

DEFINITION OF CHILD

- Children will now be defined as individuals under 18 years of age (formerly 21)
- Takes effect 01/25/16
- See [NOT-OD-16-010](#)

INCLUSION FORMS

- **New (optional) PHS Inclusion Enrollment Report form**
- **Replaces (optional) Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms**
- **More details will be provided prior to release**
- **Takes effect 05/25/16**

RESEARCH TRAINING DATA TABLES

- New tables will be used in T applications; where specified, may also be used in K and R25 applications
- New xTRACT system used to create and store information in research training data tables
 - Applicants may continue to use [blank data tables](#)
- Other changes include:
 - Number of tables reduced from 12 to 8
 - Reporting of individual-level information minimized
 - Tracking of trainee outcomes extended from 10 to 15 years
- Takes effect 05/25/16
- See [NOT-OD-15-112](#), [NOT-OD-16-007](#), and [sample tables](#)

DATA SAFETY MONITORING PLAN

- **New attachment required for all applications involving clinical trials**
- **This requirement is not new, but this information will now be provided in a separate attachment**
- **Takes effect 05/25/16**
- **See [NOT-OD-16-004](#)**

APPENDIX POLICY

- **Current appendix policy under review**
- **Specific changes will be announced in Spring 2016 and will take effect in Phase 2**
- **Changes may affect documents allowed in the appendix section**

FONT GUIDELINES

- Recommended fonts: Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana
- Other fonts are acceptable if they meet the following additional requirements:
 - Size: 11 points or larger
 - Density: No more than 15 characters per linear inch
 - Spacing: No more than six lines per vertical inch
 - Color: Black
- Takes effect 05/25/16
- See [NOT-OD-16-009](#)

BIOGRAPHICAL SKETCH

- **In effect since 05/25/15**
- **5 pages**
- **Personal Statement**
 - **Include up to four research products**
 - **Optional: Include link to full list of products, but must link to a government website**
- **Contributions to Science**
 - **Describe up to five contributions**
 - **Include up to four research products per contribution**
- **Graphics, figures, and tables are not allowed**

SALARY CAP

- NIH salary cap has increased
 - \$185,100 (12 month)
 - \$138,825 (9 month)
- **Reminder: Provide actual base salary in application budgets and explain that actual institutional base salary exceeds the current salary limitation**
- **In effect 01/10/2016**
- See [NOT-OD-16-045](#) and UT Fiscal Policy [FI0208](#)

POST-AWARD UPDATES

RESEARCH PERFORMANCE PROGRESS REPORTS

- **New RPPR change, effective 01/25/16**
- **For all annual non-competing (Type 5)**
- **Rigor and Transparency:**
 - **Clarify long-standing expectations to ensure that NIH is funding the best and most rigorous science**
 - **Highlight the need for awardees to describe details that may have been previously overlooked**
 - **Prepare non-competing renewals for the next competitive renewal**
 - **Will help NIH implement and evaluate the policy for both current and new awards**
- **See [NOT-OD-16-031](#)**

SALARY CAP

- This salary limitation is mandated by Congress
- The “Executive Level II” salary increased to \$185,100 Effective 01/10/16
- No adjustment will be made to a grant award (competing or non-competing) already issued in FY 2016
- Always include accurate base salary in proposal
- Rebudgeting is allowed
- Full details available at [NOT-OD-16-045](#)

FAPIIS

- **FAPIIS - Federal Awardee Performance and Integrity Information System**
- **Includes government-wide data with specified information related to the integrity and performance of entities awarded Federal grants and contracts**
- **Begins 01/01/16, however as NIH implements requirements and develops policy, more information will be provided**
- **See [NOT-OD-16-019](#)**
- **Additional information available at <https://www.fapiis.gov>**

xTRACT

- Electronic system for creating research training data tables and storing the information reported in those tables for RPPRs
- Reduces the number of tables from 12 to 8
- Minimize the reporting of individual-level information
- Extend the tracking of trainee outcomes from 10 to 15 years
- Must be used for RPPRs due 12/01/15 forward
- See [NOT-OD-16-007](#) and [NOT-OD-15-112](#)

INCLUSION MANAGEMENT SYSTEM

- **Updates coming to the screens in the Inclusion Management System (IMS)**
- **More information will be posted in a Guide Notice just prior to when the changes will be implemented**
- **Target effective date is 01/22/16**

UNIFORM GUIDANCE

- **OMB Circulars A-21, A-87 and A-122 have been consolidated into a single source document relocated to 2 CFR Part 200, Subpart E - Cost Principles**
- **NIH implementing at 45 CFR Part 75**
- **Effective for Notices of Award (NoA) issued on or after 12/26/14 that obligate new or supplemental funds**
- **NoAs issued on or after 12/26/14 that do not involve obligation of new or supplemental funds remain subject to 45 CFR Part 74 until new funds are obligated**

UNIFORM GUIDANCE

- **The cost principles still require four tests to determine the allowability of costs**
 - **Reasonableness (includes Necessity)**
 - **Allowable**
 - **Allocability**
 - **Consistency**

UNIFORM GUIDANCE

- **You can still do the following:**
 - **Insure pre-award costs up to 90 days before the beginning date of the initial budget period of a new or renewal award**
 - **Initiate a one-time extension of the final budget period of a previously approved project period without additional funds**
 - **Carry forward unobligated balances from one budget period to any subsequent budget period**
 - **Rebudget among budget categories**
 - **Rebudget between direct and indirect costs**
 - **Provide subawards based on fixed amounts provided they meet the requirements for fixed amount awards in 45 CFR 75.201**

QUESTIONS?

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