

# 2017 NIH Update

Presented by  
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THE UNIVERSITY OF  
TENNESSEE  
KNOXVILLE

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OFFICE OF RESEARCH &  
ENGAGEMENT

# PRESENTERS



**Stephanie Smith**

**Post-Award  
Office of Sponsored Programs**



**Stacey Wade**

**Pre-Award  
Office of Sponsored Programs**

# NIH INSTITUTES

- National Cancer Institute (NCI)
- National Eye Institute (NEI)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)

# NIH INSTITUTES CONT.

- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

# NIH INSTITUTES CONT.

- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)

# NIH INSTITUTES CONT.

- National Institute of General Medical Sciences (NIGMS)
- National Institute of Mental Health (NIMH)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Nursing Research (NINR)

# NIH INSTITUTES CONT.

- National Library of Medicine (NLM)

# NIH CENTERS

- NIH Clinical Center (CC)
- Center for Information Technology (CIT)
- Center for Scientific Review (CSR)
- Fogarty International Center (FIC)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Complementary and Integrative Health (NCCIH)



# PRE-AWARD UPDATES

# Updated Guidelines

- **The most recent guidelines were updated Nov. 22, 2016.**
- **Form instructions have been reordered to match the order of appearance in the application package.**
- **Clarified existing instructions.**

# APPLICATION COMPLIANCE

## ▶ Application Form Instructions [SF424 (R&R) -Version D]

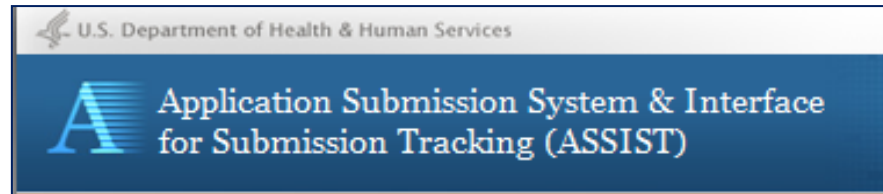
\* See funding opportunity announcement for forms \*

[Need help selecting the right application instructions?](#)

Application Instructions	Description	View/Download
General (G) Instructions	Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications	<a href="#">HTML</a> <a href="#">PDF</a>
<b>Filtered views for your convenience:</b>		
Research (R) Instructions	Guidance for research only	<a href="#">PDF</a>
Career Development (K) Instructions	Guidance for career development only	<a href="#">PDF</a>
Training (T) Instructions	Guidance for training only	<a href="#">PDF</a>
Fellowship (F) Instructions	Guidance for fellowship only	<a href="#">PDF</a>
Multi-Project (M) Instructions	Guidance for multi-project only	<a href="#">PDF</a>
SBIR/STTR (B) Instructions	Guidance for small business only	<a href="#">PDF</a>
Supplemental Instructions	Instructions on preparing the protection of human subjects section of the research plan and human subjects research policy, as well as additional policies, assurances, definitions, and other information	<a href="#">PDF</a>

# SUBMITTING YOUR APPLICATION

- Cayuse 424
- ASSIST
- Grants.gov forms



# Font Guidelines

- **Effective Jan. 25, 2017 (see Notice [NOT-OD-17-030](#)):**
  - **Text Color:** No restriction but black is recommended
  - **Font size:** Must be 11 points or larger. Smaller text in figures, graphs, diagrams, and charts is allowed as long as they are legible
  - **Type density:** No more than 115 characters per linear inch
  - **Line spacing:** No more than six lines per vertical inch
  - **Recommended fonts:** Arial, Georgia, Helvetica, Palatino Linotype
  - **NOTE:** Since some PDF converters may reduce font size, it is important to confirm that the final PDF document complies with the font requirement

# Cover Letter Attachment

- **When to use:**
  - For late applications
  - For changed/corrected applications submitted after the due date
  - Explanation of any subaward budget components not active for all periods of the proposed grant
  - Statement that you have attached any required agency approval documentation for the type of application submitted. The approval documentation should be attached to the cover letter
  - When intending to submit a video as part of the application
  - Include statement if the proposed studies will generate large-scale human or non-human genomic data

# Cover Letter Attachment

- **When not to use:**
  - To request assignment
  - For anything other than the six items on the last slide

# 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
- See [NOT-OD-16-008](#)



# APPENDIX

- **Effective Jan. 25, 2017 (see Notice [NOT-OD-16-129](#))**
  - **Allowable appendix materials**
    - **Blank informed consent/assent forms**
    - **Blank surveys, questionnaires, data collection instruments**
    - **FOA-specific items. Only when required by FOA**

# APPENDIX

- **Effective Jan. 25, 2017 (see Notice [NOT-OD-16-129](#))**
  - **Unallowable appendix materials**
    - **Everything not listed on previous slide**
    - **All information required for peer review process must be contained within those designated sections of the application, unless the FOA states otherwise**
- **Consequences for submitting disallowed appendix materials:**
  - **Proposal will be withdrawn and not reviewed**

# Requesting more than \$500,000 Direct Costs

- [NOT-OD-17-005](#)
  - Unsolicited applications that exceed \$500,000 in direct costs now have the option to submit the request electronically through eRA Commons, under the new Prior Approval Module.
  - After initial communication with NIH, a Program Officer can open up a request form for the PI in Commons. The PI will complete the form and submit to the PO for review.

# Post-Submission Materials

- **[NOT-OD-16-130](#)**
  - NIH has simplified and consolidated the current policy concerning post-submission materials (submitted after submission of the proposal but before initial peer review)
  - Materials must be received by the Scientific Review Officer no later than 30 calendar days prior to the peer review meeting.
  - Must be submitted as a PDF via email to the SRO. The materials must be sent by the AOR or, if the PD/PI submits, the AOR must send his/her concurrence to the PD/PI who then forwards it on to the SRO

# Post Submission Materials (cont.)

- **Allowable materials:**
  - **Revised budget page(s) (e.g. due to new funding or institutional acquisition of equipment)**
  - **Biographical sketch (e.g. due to the hiring, replacement, or loss of an investigator)**
  - **Adjustments resulting from natural disasters (e.g. lost of an animal colony)**
  - **News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel**
  - **News of an article accepted for publication since submission of the application**
    - **Must include only:**
      - **List of authors and institutional affiliations**
      - **Title of the article**
      - **Journal or citation**

# Ruth L. Kirschstein National Research Service Awards

## Postdoctoral Stipend levels for FY 2017

Career Level	Years of Experience	Actual Stipend for FY 2016	Stipend for FY 2017	Monthly Stipend
Postdoctoral	0	\$43,692	\$47,484	\$3,957
	1	\$45,444	\$47,844	\$3,987
	2	\$47,268	\$48,216	\$4,018
	3	\$49,152	\$50,316	\$4,193
	4	\$51,120	\$52,140	\$4,345
	5	\$53,160	\$54,228	\$4,519
	6	\$55,296	\$56,400	\$4,700
	7 or More	\$57,504	\$58,560	\$4,880

**NOT-OD-17-003**

# BIOGRAPHICAL SKETCH

- **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**
- **Note: Fellowship proposals require a slightly different format**

# SALARY CAP

- **NIH salary cap**
  - \$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 since 01/10/2016**
- **See [NOT-OD-16-059](#) and UT Fiscal Policy [FI0208](#)**



# **ADDITIONAL ITEMS TO NOTE:**

- **Mentors must provide a Commons username for Career applications**
- **On Modular Budgets, the Indirect Costs section has been changed to dynamically add indirect costs rather than having to type in the number**
- **When using human subjects, remember to complete the PHS Inclusion Enrollment Report**
- **UT has a new Animal Assurance No. D16-00397. The previous number is still active but we need to transition to the new one.**

# POST-AWARD UPDATES

# FINAL RESEARCH PERFORMANCE PROGRESS REPORTS

- **New Final RPPR change, effective 01/01/2017**
- **Final RPPR will replace the FPR**
- **Format will be the same**
- **Renewal (Type 2) application un consideration**
  - **Submit an "Interim-RPPR" while the renewal application (Type 2) is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPR.**

# **FINAL RESEARCH PERFORMANCE PROGRESS REPORTS Cont.**

- **Requirement to report on Project Outcomes.**
  - **This section will be made publicly available, thus allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).**
- **NIH is aligning its reporting requirement with other Federal research agencies and therefore will not be making any changes to the deadline for submitting the final report- i.e., the Final RPPR or Interim-RPPR must be submitted via eRA Commons no later than 120 calendar days from the period of performance end date.**

# FINAL RESEARCH PERFORMANCE PROGRESS REPORTS Cont.

- See [NOT-OD-17-022 and 037](#)
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-037.html>
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-022.html>

# SALARY CAP

- There are no changes
- 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 and 046](#)
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-045.html>
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-046.html>

# FAPIIS

- **FAPIIS - Federal Awardee Performance and Integrity Information System**
- **Began 02/16/16**
- **Includes government-wide data with specified information related to the integrity and performance of entities awarded Federal grants and contracts**
- **Applies to all NIH grants and cooperative agreements, except fellowships**

# FAPIIS Cont.

- NIH Institutes and/or Centers (ICs) will review any information in FAPIIS and consider whether a recipient continues to demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements and procurement contracts; or its integrity and business ethics.
- If an institution does not fully meet these standards, an award may still be considered if it is determined that the information in FAPIIS is not relevant to the current NIH award under consideration or if there are specific conditions that can appropriately mitigate the effects of any identified risk.
- See [NOT-OD-16-067](#)
- <https://www.fapiis.gov>



# NIH GRANTS POLICY STATEMENT

- **Effective 11/2016**
- **Applies to all grants and cooperative agreements with budget periods beginning on or ending after 10/01/16.**
- **There are changes**
- **See [NOT-OD-17-021](#)**
- **<https://grants.nih.gov/policy/nihgps/index.htm>**
- **[http://grants.nih.gov/grants/policy/nihgps/Significant\\_Changes\\_NIHGPS\\_Oct2016.pdf](http://grants.nih.gov/grants/policy/nihgps/Significant_Changes_NIHGPS_Oct2016.pdf)**

# PROTECTIONS OF HUMAN SUBJECTS

- **Final rule to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects (Common Rule).**
- **Enhance protections for human research participants, facilitate valuable research, and reduce burdens for investigators, research institutions, and Institutional Review Boards (IRBs)**
- **Effective 01/2018**
- **Studies that have not yet undergone initial IRB review will be subject to the new requirements on that date.**

# PROTECTIONS OF HUMAN SUBJECTS Cont.

- Research ongoing on that date will continue to be subject to the current Common Rule requirements unless an institution chooses to comply with the final rule requirements for ongoing studies as well
- HHS intends to issue further guidance on specific provisions of the rule.
- NIH will be working with the Office for Human Research Protections in the coming months to develop additional guidance for the research community and, as necessary and appropriate, NIH will update relevant policies.
- See [NOT-OD-17-038](#)
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-038.html>

# QUESTIONS?

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