Research Administration and Compliance Meeting  
Wednesday, August 17, 2016  1:00 – 3:00 p.m. 
Ball Conference Room, BioTech I  

Agenda 

Grants & Contracts Accounting  
• G&C Staff Update  
• Associate Vice President for Sponsored Programs Search Update  
• New Banner XE platform scheduled for potential October implementation - Awareness and status of testing  

Clinical Research Updates  
• Cerner/OnCore Integration Update  

Special Guest  
• Scientific Review Committee – Jennifer Economy  

Office of Sponsored Programs  
• Process Changes (or not) associated with RAMS-SPOT Phase II Functionality  

Office of Export Compliance  
• Export and FCPA Training Offerings  

Office of Research Administration and Compliance  
• Allowable Post-Submission Materials for NIH applications effective January 25, 2017  
• Allowable Appendix Materials for NIH applications effective January 25, 2017  
• Proposed NRSA Stipends effective December 1, 2016  
• Research Expo 2016 – October 20, 2016  Register here:  http://research.vcu.edu/expo/  

Office of Research Integrity and Ethics  
• No Report  

Office of Research Subjects Protection  
• No Report
Research Administration and Compliance Meeting
August 17, 2016
Grants & Contracts Accounting Updates
G&C staff and misc. updates

- Welcome Juliette Highland, Supervisor, Effort Reporting
- New Accountants: Angela Brown-Conklin from School of Engineering starting 8/25/2016; Linda Gillis from VDOH also starting 8/25/2016
- Updated Org chart
New-Associate Vice President for Office of Sponsored Programs

- National search – ejobs, other professional websites (NCURA, COGR, NACUA, Diverse, etc.)
- Required Education – Juris Doctorate
- Required Experience – 10 years sponsored project admin. at a research university
- Direct report to Dr. Macrina
• Tina Cunningham based on ratings from campus visit groups/interviews unanimously recommended for hire by Search Committee
• Offer made and accepted
• Starting date 10/1/2016
New Banner XE platform - awareness

- Banner XE is Ellucian's replacement for our current version of Banner Forms.
- General, HR and Finance forms are fully functional in XE. Student, FinAid and AR won't be fully functional in XE until the Spring of 2017.
- Testing is currently taking place in all central admin areas.
New Banner XE platform, cont.

- The Banner XE home page looks like a web search page.
New Banner XE platform, cont.

Type in form name and press enter key:
New Banner XE platform, cont.
New Banner XE platform, cont.

Results are shown. Use the scroll bar on right side of page or the up and down keys to navigate the information.
Questions???

Thanks for your continued assistance.
Grants and Contracts Accounting/Effort Reporting

Mark Roberts
OnCore – Cerner Integration

Bobby Moulden
rbmoulden@vcu.edu
oncore@vcu.edu
Overview

Cerner to OnCore

• Reduces data entry by auto-populating demographic fields in OnCore from Cerner. Updates in Cerner are updated automatically in OnCore

OnCore to Cerner

• Improves patient safety by indicating in Cerner a patient’s research participation
Cerner to OnCore

Status: Completed May 24th 2016

Cerner data sent to OnCore:

- First Name
- Last Name
- Middle Name
- Suffix
- Birth Date
- Gender
- Race
- Ethnicity
- Contact Information
OnCore to Cerner

Status – Expected Completion in September
  • Final VCUHS IT Testing underway
  • Loading of existing study and participant date to be completed

OnCore Data Sent to Cerner:

Protocol Fields:
  • Sponsor Protocol Number
  • Short Title
  • NCT Number
  • IRB Number
  • Protocol Status and Status Date
  • Staff (PI, Study Coordinator)

Participant Fields:
  • Associated Protocol
  • Participation Status and Date
  • Sequence Number (Enrollment ID)
VCU Scientific Review Committee Overview

Mission

VCU is committed to ensuring that human subject research conducted at the institution is scientifically sound and feasible: The Scientific Review Committee (SRC) at Virginia Commonwealth University provides study design, analytic planning and operational feasibility review of clinical research before review by the IRB.

The SRC’s mission is to ensure that all research projects involving humans at Virginia Commonwealth University meet acceptable standards of scientific rigor and feasibility without obstructing institutional efficiency and timeliness. The SRC is directly linked to the goals and strategies of VCU’s Quest for Distinction, Theme II which aims to “Attain distinction as a fully integrated urban, public research university through contributions in human health, research, scholarship and creative expression that advance knowledge and enhance the quality of life.”

Formation of an effective SRC will place VCU in alignment with the NIH NCATS vision of the future that currently is being adopted by other leading research universities

Purpose

The SRC is an integral part of the VCU system of research that involves living human beings that operates under the office of the Vice President for Research and Innovation.

The SRC functions in collaboration and in cooperation with all other entities of that office dedicated to human research. Its primary purpose is to assure the quality of research proposals being submitted to the IRB for full board review.

Leadership and Membership

<table>
<thead>
<tr>
<th>VCU SCIENTIFIC REVIEW COMMITTEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>David X. Cifu, MD</td>
</tr>
<tr>
<td>Chair</td>
</tr>
<tr>
<td>Physical Medicine and Rehabiliation</td>
</tr>
</tbody>
</table>

| Antonio Abbate, MD, PhD       |
| Associate-Chair               |
| Cardiology                    |

| James Bjork, PhD             |
| Core Member                  |
| Neuroscience                 |

| Pamela Dillon, PhD PharmD    |
| Core Member                  |
| Pharmacology                 |

| Deborah McGuire, RN, PhD     |
| Core Member                  |
| Nursing                      |

| Sinem Esra Sahingur, DDS/MS/PhD |
| Core Member                  |
| Periodontics                 |

| Jacob Wegelin, PhD           |
| Core Member                  |
| Biostatistics                |

| Ananda Amstadter, PhD        |
| Ad Hoc Member                |
| Psychiatry                   |

| Jan Arrowood, MD             |
| Ad Hoc Member                |
| Cardiology                   |

| Jasmohan Bajaj, MD           |
| Ad Hoc Member                |
| Hepatology/Encephalopathy    |

| Sherman Baker, MD            |
| Ad Hoc Member                |
| Hematology/Oncology          |

| Gretchen Brophy, PharmD      |
| Ad Hoc Member                |
| Pharmacotherapy & Outcomes |
| Science                     |

| Jonathan Deshazo, PhD       |
| Ad Hoc Member                |
| Health Informatics           |

| Gary Francis, MD            |
| Ad Hoc Member                |
| Pediatrics                  |

| Stephen Kates, MD           |
| Ad Hoc Member                |
| Orthopedic Surgery          |

| Alexander Krist, MD, PhD    |
| Ad Hoc Member                |
| Family Practice, Community  |

| F. Gerard Moeller, MD       |
| Ad Hoc Member                |
| Psychiatry                  |

| Elizabeth Ripley, MD        |
| Ad Hoc Member                |
| IND/FDA Nephrology          |

| Benjamin Van Tassell, PharmD|
| Ad Hoc Member                |
| Pharmacotherapy & Outcomes  |
| Science                     |

| Kelli Williams-Gary, PhD    |
| Ad Hoc Member                |
| Occupational Therapy        |

| Francis Macrina, PhD        |
| Vice President for Research |
| and Innovation              |

| Michelle Stuckler, DEd     |
| Director, Office of Research | Subject Protocols          |

If you have any questions or concerns, please do not hesitate to contact Jennifer Economy
Email: jennifer.economy@vcuhealth.org/ Work Phone: 804-827-0472/ Cell: 804-514-6360
Website: http://www.ccitr.vcu.edu/src/
Office of Sponsored Programs (OSP) Updates:
Annie Publow
Director, OSP-Government/Nonprofit
RACM, August 17, 2016
OSP Update Topics

Process Changes (or not) associated with RAMS-SPOT Phase II Functionality:

- Documentation for Administrative Actions (AA)
- When to process a Continuation Proposal (CP)
- Implications of “Stand alone” agreement or “Amendment” on Funding Proposal (FP)
- Making changes to committed effort
- Requesting issuance of a subaward/subcontract
- Submitting Closeout documentation
- Queries to OSP/What reference number to include
RAMS-SPOT Phased Implementation

Phase 2: Compliance Data, Awards, Continuation/Supplement Proposals, and Administrative Actions

Go Live: May 31, 2016...Included these functions:

- Compliance Data (Subjects Protection, Intellectual Property, Export Control, Hazardous Materials, rDNA, HIPAA, Controlled Substances, Clinical Trial)
- Award processing (initial and subsequent actions)
- Funding Proposal Continuations/Supplements
- Administrative Actions (No Cost Extension, Progress Report, Effort Change, Change to Fiscally Administering Unit (FAU), Change of PI, Grant Relinquishment, etc.)
RAMS-SPOT Phased Implementation

Phase 3: Closeout, Subrecipients and Reporting

➢ Target Go Live: December, 2016...Will Include:
  • Subrecipient Actions
  • Closeout
  • Reporting

[Spoiler alert: Because subrecipient and closeout processes are not yet developed for RAMS-SPOT, there is no change to previous process.]
OSP Update

Process Changes (or not) associated with:

➤ Administrative Actions (AA)
   - Transaction routing form previously provided guidance on documentation needed to support your request.
   - We’re in transition in terms of providing you with detailed guidance on what OSP needs to complete its review and sign, submit and/or process your request.
   - In all cases, we certainly need whatever is called for by the sponsor terms and conditions, NOA, or executed agreement.
   - Administrative Actions “Process Award” and “Process Closeout” are for OSP use only.
OSP Update

Process Changes (or not) associated with:

- **Administrative Actions (AA)**
  - We are developing a guidance document that will be posted to our website. There will be a training session in September to launch the use of the guidance document.

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**RAMS-SPOT ADMINISTRATIVE ACTION GUIDANCE**

[Green background signifies expanded authority; no fill signifies prior approval request.]

<table>
<thead>
<tr>
<th>Administrative Action</th>
<th>Documentation provided by PI/SS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carryforward of unobligated balances from one budget period to the next</td>
<td></td>
</tr>
</tbody>
</table>
  - G&C Accounting handles  
  - Documentation required by sponsor terms and conditions, NOA or executed agreement  
  - Letter signed by PI (on VCU letterhead) to Sponsor Grants Management, cc: to Program Officer. AOR countersigns.  
  - Supporting budget  
  - All related correspondence |

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OSP Update

Process Changes (or not) associated with:

- When to process a Continuation Proposal (CP)
  - When there is additional funding for additional or continued scope of work (that was not documented in initial FP)
  - When there is additional funding/scope of work that is likely to be awarded by the sponsor via an amendment/modification
  - When the initial FP authorized commitment of resources for only a portion of funding that actually is received.

- CP is indicated when there is requested funding beyond what was recorded in the initial funding proposal (FP)
OSP Update

Process Changes (or not) associated with:

When to process a Continuation Proposal (CP)

- Implications of “stand alone” agreement vs. “amendment/modification” on Funding Proposal (FP) or Continuation Proposal (CP)
- What do we mean by “stand alone” agreement?
- What do we mean by agreement “amendment/modification”?
“Stand Alone” Agreements

Award Year 1

FDP Cost Reimbursement Research Subaward Agreement

Pass-through Entity (PTE): George Mason University

Subrecipient: Virginia Commonwealth University

PTE Principal Investigator (PI): Dr. Campbell

Subrecipient Principal Investigator (PI): Dr. Algar

PTE Federal Award No.: 1R01WW06753

FAIN:

Federal Award Issue Date: Jul 25, 2017

Total Amount of Federal Award to PTE: $500,000.00

CFDA No.: 93.123

CFDA Title:

Federal Awarding Agency: NIH

Project Title: VCU Pilot Program

Subaward Period of Performance:

Start: Aug 1, 2016

End: Jul 31, 2017

Amount Funded This Action: $25,000.00

Subaward No.: 1-VCU1968

Incrementally Estimated Total:

Yes or No

Is this Award R & D:

Check all that apply:

☐ Reporting Requirements (Attachment 4)

☐ Subject to FFATA (Attachment 3B)

☐ Cost Sharing (Attachment 5)

Terms and Conditions

1) PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are (check one) _____ as specified in Subrecipient’s proposal dated or _____ as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2) PTE shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient’s standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party’s Financial Contact, as shown in Attachments 3A.

Noteworthy features:

- Full terms and conditions.
- New award number.
- No reference to modification or amendment to an existing an award.
- If Y1 only identifies a single year of performance, it can be an indication that we’ll receive another stand alone agreement for Y2 (period of performance -project period)
Agreement Amendments

Noteworthy features:

- Only changes to terms and conditions are identified.
- Clearly marked as an amendment to the existing subaward number.
- OSP awards and tracks as part of the existing award.
- If original FP did not cover the period and dollars awarded with this action, a CP to the original FP will be needed for the addition: SOW/funding.
“Stand Alone” Agreements

Noteworthy features:

- Sometimes Y2 of a subaward is issued as an independent award from Y1.
- Sponsor assigns new subaward number (which may be similar to existing award).
- Despite being issued under the same prime award, and continuing the SOW, VCU must track this award separately with a new FP#.
Agreements with Amendments to follow

- If the sponsor’s initial agreement estimates the full project period and budget to be incrementally awarded, it is often an indication that an amendment will follow for the next award period.
How does the form of the agreement affect the proposal?

Scenarios:

1. Initial FP proposed for 5 years; 5 year budget and SOW
   Sponsor awards initial stand alone agreement. Sponsor awards agreement modification/amendments for Y2-Y5.
   - No additional FP or CP needed if dollars and SOW are the same or less than initial FP.

2. Initial FP proposed for 5 years; 5 year budget and SOW
   Sponsor awards initial stand alone agreement for Y1. Sponsor awards stand alone agreements for each subsequent year (Y2, Y3, Y4, Y5)
   - Additional FP needed for Y2, Y3, Y4, Y5 (original FP cannot be copied)
How does the form of the agreement affect the proposal?

Scenarios (cont):

3. Initial FP proposed for 1 year; 1 year budget and SOW
Sponsor awards initial stand alone agreement. Sponsor awards agreement modification/amendments for Y2-Y5.

- Additional CP needed for Y2-Y5. Can either create one CP to cover Y2-Y5, or create a CP for each of the follow-on years.

4. Initial FP proposed for 1 year; 1 year budget and SOW
Sponsor awards initial stand alone agreement. Sponsor awards stand alone agreements for each subsequent year (Y2, Y3, Y4, Y5)

- Additional FP needed for Y2, Y3, Y4, Y5 (original FP cannot be copied. Cannot use CP.)

Remember: if you create an FP that should be a CP, or vice versa, OSP can correct.
## OSP Update

Process Changes (or not) associated with:

- Changes to committed effort

<table>
<thead>
<tr>
<th></th>
<th>Named Key Personnel</th>
<th>Vs.</th>
<th>Internal Key Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Processes</strong></td>
<td>Committed effort is captured and tracked in RAMS-SPOT for named key personnel</td>
<td></td>
<td>Proposed effort for internal key personnel is captured, but not tracked, in RAMS-SPOT</td>
</tr>
<tr>
<td><strong>Definitions</strong></td>
<td>Named key - an individual critical to the conduct of the project and named by the sponsor in the agreement or award document</td>
<td></td>
<td>Internal Key - a VCU employee with a VCU faculty appointment or a VCU employee designated by the PI as key personnel</td>
</tr>
<tr>
<td></td>
<td>Committed effort - the minimum level of effort approved by the sponsor</td>
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</tr>
</tbody>
</table>
| **Variances**           | A variance in committed effort for named key personnel typically requires the sponsor’s written prior approval. Examples include:  
• Significant reduction (≥ 25%) in effort  
• Significant absence (≥ 3 months) from the project  
• Complete disengagement or substitution  
• Any change in effort as stipulated in agreement/award |                                                                     | A variance from proposed effort is not captured or tracked                                |
| **Procedures**          | Submit an Administrative Action of a type appropriate for the specific situation (Personnel: Change Effort / Personnel: Change PI / Personnel: PI Disengagement) and attach supporting documentation, such as a written request for approval |                                                                     | No action is needed                                                                       |
OSP Update

Process Changes (or not) associated with:

- Requesting issuance of a subaward/subcontract
  - No change to previous process
  - Use subaward request forms available on OSP website: [http://www.research.vcu.edu/forms/index.htm#osp_forms](http://www.research.vcu.edu/forms/index.htm#osp_forms)
  - Subaward Request and Subaward Amendment Request forms (with pertinent documentation) should continue to be emailed to ospaward@vcu.edu
  - Phase III implementation will include functionality for subawards and storage of subaward documentation, however, the process until then is fully manual and documentation must be maintained outside of the database (by both OSP and PI/SS)
  - Questions should continue to be directed to ospaward@vcu.edu
OSP Update

Process Changes (or not) associated with:

- Submitting Closeout documentation
  - No change to previous process
  - Use e-closeout forms available on OSP website:
    http://www.research.vcu.edu/forms/index.htm#osp_forms
OSP Update

Process Changes (or not) associated with:

- Queries to OSP by phone or email...What reference number to include?
  - Funding Proposal Number

- You can also include the Banner index, PD/PT/SC# but you must include the FP# for fastest response
Introduction to Export Controls

Quinton Johnson
Director, Export Compliance Office
Office of the Vice President for Research and Innovation
International Travel Management

- Christopherson
  - Receive daily travel reports and notify all travelers about basic export and FCPA concerns

- Chrome River
  - Countries deemed “high risk”
  - Receive pre-approval requests through Chrome River
**International Travel Training Update**

- Mandatory Training for all International Travelers
  - Training will be available quarterly, beginning in January 2017 (quarterly session will be split between both Medical and MP campuses)
  - Training must be renewed every 2 years
  - Training will cover export compliance, foreign corrupt practices, and general international travel safety
  - There will be an alternate training for individuals who cannot make a quarterly session
- Reminders will be posted on the International Travel webpage
  - Research Expo 2016 Export Control session will meet training requirements
Contact Information

• Quinton Johnson
  Director, Export Compliance Office
  • exportctrl@vcu.edu
  • qjohnson3@vcu.edu
  • (804) 827-6088
• VCU Webpage
  • http://www.research.vcu.edu/export_control/
  • http://www.internationaltravel.vcu.edu/
New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017

Notice Number: NOT-OD-16-129

Key Dates

Release Date: August 12, 2016

Related Announcements

NOT-OD-16-130
NOT-OD-11-064
NOT-OD-11-080

Issued by

National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
National Institute for Occupational Safety and Health (NIOSH)

Purpose

This Notice alerts the scientific research community of plans to eliminate most appendix materials for applications submitted to the NIH, AHRQ or NIOSH for due dates on or after January 25, 2017. Application instructions will be updated by November 25, 2016 to reflect this change.

The Notice also clarifies:

- Status of appendix materials in peer review
- Allowable appendix materials
- Consequences for submitting disallowed appendix materials

The NIH, AHRQ, and NIOSH strive to ensure fairness in peer review for all grant applicants by specifying the types and amount of application material that are accepted for peer review. At the same time, these agencies appreciate both the need for applications to provide sufficient information to allow for an informed, expert review process and the importance of limiting the burden on peer reviewers.

Elimination of most appendix materials is intended to rectify inequities in the peer review process that can arise from submission of inappropriate or excessive appendix materials by some applicants and consideration of appendix materials in peer review by some, but not all reviewers.

Policy

Appendix materials in peer review

All information submitted with an application except the cover letter, assignment request form and appendix information are assembled into a single application image for funding consideration. The different sections within the application image are specified in the application instructions and correspond to the standard review criteria.

Therefore:

- All information required for the peer review process must be contained within those designated sections of the application image, unless the Funding Opportunity Announcement (FOA) specifies otherwise.
- Information that expands upon or complements information provided in any section of the application -- even if it is not required for the review -- is not allowed in the appendix unless it is listed in the allowed appendix materials (below). (NOT-OD-11-080)
Unless the FOA requires that certain information be included in the appendix, failure of reviewers to address appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review (NOT-OD-11-064).

Allowable appendix materials
Beginning with applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2017, the only allowable appendix materials are:

- For applications proposing clinical trials (unless the FOA provides other instructions for these materials):
  - Clinical trial protocols
  - Investigator's brochure from Investigational New Drug (IND), as appropriate

- For all applications:
  - Blank informed consent/assent forms
  - Blank surveys, questionnaires, data collection instruments
  - FOA-specified items.
    - If appendix materials are required in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.

Consequences for submitting disallowed appendix materials
Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.

Inquiries

Please direct all inquiries to:

Division of Receipt and Referral
Center for Scientific Review (CSR)
National Institutes of Health
Telephone: 301-435-0715
Email: csrdrr@mail.nih.gov

Sally A. Amero, Ph.D.
NIH Review Policy Officer
Email: ReviewPolicyOfficer@mail.nih.gov

Francis D. Chesley, Jr., M.D.
Director, Office of Extramural Research, Education, and Priority Populations
Agency for Healthcare Research and Quality
Telephone: 301-427-1521
Email: Francis.Chesley@ahrq.hhs.gov

Viji Potula, Ph.D.
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Telephone: 404-498-2551
Email: VPotula@cdc.gov
Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH... Turning Discovery Into Health®

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.
Changes to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017

Notice Number: NOT-OD-16-130

Key Dates
Release Date: August 12, 2016
Implementation Date: Applications submitted for the January 25, 2017 due date and thereafter.

Related Announcements
NOT-OD-16-129
NOT-OD-12-111
NOT-OD-12-141

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
National Institute for Occupational Safety and Health (NIOSH)

Purpose

This Notice simplifies and consolidates current NIH and AHRQ policy concerning post-submission materials, and extends this policy to NIOSH. Post-submission application materials are those submitted after submission of the grant application but prior to the initial peer review. The policy is based on the principle that, for the majority of applications, the only post-submission materials that these agencies will accept are those resulting from an unforeseen event. The policy on post-submission application materials is not intended to correct oversights/errors discovered after submission of the application.

Policy

**Allowable Post-Submission Materials for All Applications**

- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application (see NOT-OD-12-111)
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Applicants must follow the directions in NOT-OD-12-141 for submitting videos to accompany grant applications
- Other post-submission materials specified in the FOA for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application**, which must include only:
  - List of authors and institutional affiliations
  - Title of the article
  - Journal or citation (if available)
Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Funding Opportunity Announcement (FOA) for which the application was submitted or a special Guide Notice.

Additional Materials for Certain Applications

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news - since the training grant application was submitted - of:

- a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- a faculty member's promotion, funding, or publications; and
- the addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).

Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications: in addition to the materials for All Applications listed above:

- New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH/AHRQ/NIOSH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- News of change in Mentor(s) or other Senior/Key Persons specified in the original application.

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference Grant Applications (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Any other types of post-submission materials are not likely to be accepted.

Requirements for Submitting Post-Submission Materials

All post-submission materials must conform to NIH/AHRQ/NIOSH policies on font size, margins, and paper size as referenced in the applicable application instructions.

- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.
- If post-submission material is not required on a specific format page and does not have a specified page limit, each explanation or letter is limited to one page.
- If the application has multiple components (subprojects or cores), each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Post-submission materials must be received by the NIH, AHRQ, or NIOSH Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted if fewer than 30 calendar days remain before the peer review meeting, unless specifically stated otherwise in the FOA for which the application was submitted or in a special Guide Notice.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or organizational officials, the AOR must send the materials directly to the SRO or must send his/her concurrence to the PD/PI
who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

Post-submission materials **can only** be submitted as a PDF attachment. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check his/her application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

Inquiries

Please direct all inquiries to:

Division of Receipt and Referral
Center for Scientific Review (CSR)
National Institutes of Health
Telephone: 301-435-0715
Email: csrdrr@mail.nih.gov

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**Weekly TOC for this Announcement**

NIH Funding Opportunities and Notices
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Revised: Projected FY 2017 Stipend Levels for Postdoctoral Trainees and Fellows on Ruth L. Kirschstein National Research Service Awards (NRSA)

Notice Number: NOT-OD-16-134

Key Dates
**Release Date:** August 10, 2016

Related Announcements
NOT-OD-16-131 - Rescinded
NOT-OD-16-062

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
Health Resources Services Administration (HRSA)

Purpose

This Notice revises NOT-OD-16-131 to correct an error in the effective date. The purpose of this Notice is to announce projected stipend levels for *postdoctoral trainees and fellows* supported by Kirschstein-NRSA awards in Fiscal Year (FY) 2017.

These projected new stipend levels are planned to be effective December 1, 2016. The projected new stipend levels reflect recognition of the significant contributions of postdoctoral researchers to the NIH, AHRQ, and HRSA missions, and also align with the spirit of the U.S. Department of Labor’s (DOL) recently issued revisions to the rules on paid overtime under the Fair Labor Standards Act (FLSA).

The exact stipend levels and the actual date of implementation are subject to the availability of FY 2017 appropriations and implementation of the new FLSA threshold for professional workers to be eligible for paid overtime.

**Projected Postdoctoral Stipend levels for FY2017**

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

**Background**
The new FLSA paid overtime rule sets a salary level of $47,476 for professional employees to be exempt from paid overtime.

Current NRSA stipend levels at years 0, 1 and 2 years of postdoctoral experience are below $47,476. Many universities, teaching hospitals, and other institutions that employ postdoctoral researchers use the NRSA stipend levels as a guide to set the salary or compensation levels for postdoctoral researchers funded on research.
project grants and grants other than the NRSA.

These institutions may choose to carefully track their employed postdoctoral researchers’ hours and pay overtime, or raise their salaries to levels above the new FLSA threshold and thereby qualify them for exemption from paid overtime.

NIH is fully supportive of increased pay for postdoctoral researchers and has proposed to increase the NRSA postdoctoral stipends to levels above the threshold: [http://www.huffingtonpost.com/francis-s-collins-md-PhD/fair-pay-for-postdocs-why_b_10011066.html](http://www.huffingtonpost.com/francis-s-collins-md-PhD/fair-pay-for-postdocs-why_b_10011066.html).

Stakeholders at many extramural institutions have requested information about projected NRSA stipends for FY 2017 to assist with planning for future postdoctoral researcher payscales.

This Notice is therefore provided to assist the extramural community in their planning.

It is important to note that the projected FY 2017 stipends listed here and the implementation date are still to be finalized.

**Relevant NIH Policies**

For institutional training grants (T32, T90, TL1) and individual fellowships (F32), the stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree.

Kirschstein-NRSA support for postdoctoral research training is limited to three years. The presence of eight discrete levels of experience does not constitute an endorsement of extended periods of postdoctoral research training. The NIH, HRSA and AHRQ provide eight postdoctoral stipend levels to accommodate individuals who complete other forms of health-related training prior to accepting a Kirschstein-NRSA supported position for research training.

Additional guidance on NRSA stipend levels and implementation dates will be communicated in the coming months.

**Inquiries**

Please direct all inquiries to:

Division of Biomedical Research Workforce
Office of Extramural Programs
Office of Extramural Research
Website: [https://researchtraining.nih.gov](https://researchtraining.nih.gov)
Email: NIHTrain@mail.nih.gov

**Additional Information**

Note that the interpretation and implementation of the FLSA and the DOL overtime regulations are under the authority of the DOL and the courts. While NIH plans to raise its NRSA stipends for consistency with spirit of the DOL’s support for increased pay, as reflected in its recent revisions to the overtime regulations, the NIH takes no position on the applicability of the overtime regulations to a particular worker supported by NIH grants. Institutions should consult their own counsel and/or local Department of Labor office about the applicability of the overtime regulations and for information on overtime obligations.
**Note:** For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](http://grants.nih.gov/grants/guide/notice-files/NTO-OD-16-134.html).