Agenda

RCC Update – Jim Luther & Julie Cole
Clinical Trials – Jessica Houlihan
GCP – Lorna Dula
International Update – Broderick Grady
ORA Update - Michael Dickman
RCC Update

ORA Quarterly Meeting
January 26, 2017
Julie Cole, Director
Research Costing Compliance
Topics

- QuickStart Program Update
- AGM Update
- Reminder: Continuing Education Credits
- Reminder: Evaluations
- RCC Alert and the Grants Management Community News
QUICKSTART PROGRAM

WHAT IT IS
A “quick start” in introductory knowledge and basic skill sets in Research Administration at Duke

Introduction to Research Administration at Duke
Introduction to Compliance at Duke
Introduction to Pre-Award Administration at Duke (I & II)
Introduction to Post-Award Administration at Duke (I & II)
“Capstone” Forum

Six on-demand, self-paced online training modules with companion references and step-by-step guides, with a “Capstone” hands-on class for basic skills assistance.

HOW IT WORKS
Open enrollment curriculum for self-enrollment through the Learning Management System (LMS)

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HOW IT WORKS
Open enrollment curriculum for self-enrollment through the Learning Management System (LMS)

BENEFITS
Supports onboarding of new employees with research administration responsibilities

SKILLS
With departmental support and guidance, participants will be familiar with the following skills at completion:

- Navigate the Duke GAPs
- Navigate the SPS system to support proposal development
- Process a No Cost Extension request
- Process a Cost Transfer using the CT Tool
- Read and understand Master Data
- Process cost distributions via the Grants Management tab
- Assist with processing Closeouts

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**QUICKSTART GUIDE**

This guide is designed to support supervisors during the initial 90 days of new research administrators. It is intended as recommended guidance only, and the actual assignment of duties is dependent upon department needs.

**Key Elements & Skills Provided in QuickStart**

- Understand the basic functions of research administration and how it is managed at Duke University
- Understand the basic compliance rules for research administration
- Perform limited, basic functions:
  - Perform a No Cost Extension
  - Perform a Cost Transfer using the CT Tool
  - Review/Adjust Master Data
  - Process cost distributions via the Grants Management tab
  - Assist with processing Closeouts
- **Note:** The SPS class offered by ORA is open enrollment if basic skill in SPS entry is desired as a supplement to QuickStart

**Recommended System Access for New Grant Managers**

- SPS (Sponsored Program System)
- SAP (r3 – Financial System)
- Grant Manager Tab
- Refer to the System Access Tool for further detail

**Recommended Other Training in first 90 days**

- Introduction to Duke Accounting and Business Practices
- Introduction to Duke General Ledger Accounts
- SPS (Sponsored Program System – SOM class, Campus ORS provides)
- Cost transfer (with supervision)
- No Cost Extension
- Request Basic cost distribution changes
- Closeout checklist

**Recommended 90 day assignments with initial department supervision**

- Basic post-award functions
- NOA and award setup basics
- Duke post-award systems and offices
- Basic SAP reports and GM tab
- Post-award financial function overview
- Basics of closeout and tasklist function

**ToolPak Guide**

- Enroll in “Capstone” class as soon as modules are completed
- Supervisors should guide employees as to relevant questions, additional information needed, and recommended “hands-on” training desired during the capstone experience

**“Capstone” Forum**

- Basic post-award functions
- NOA and award setup basics
- Duke post-award systems and offices
- Basic SAP reports and GM tab
- Post-award financial function overview
- Basics of closeout and tasklist function

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SAMPLE: Key Features: ToolPak, narration, navigation and script for easy reading.
SAMPLE: Animated graphics with narrative
SAMPLE: Knowledge Check
Interactive Activities during the modules to test for understanding.

Complete the *Sponsored Project Timeline* by dragging the icon to its correct space in the timeline. Click the *Submit* button when you have completed the timeline.
SAMPLE: ToolPak
Reference materials (ToolPak) are imbedded within the module for easy download. Banners remind participants to refer to a ToolPak resource when appropriate to slide content. List also available at the end of each module and in LMS.
SAMPLE ToolPak ITEM

Research Administration Systems PDF
<table>
<thead>
<tr>
<th>LIFE CYCLE STAGE</th>
<th>SYSTEM</th>
<th>WHERE TO FIND</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PROPOSAL &amp; BUDGET DEVELOPMENT</strong></td>
<td>Sponsored Projects System (SPS)</td>
<td>To gain access to SPS, contact your Pre-Award Office.</td>
</tr>
<tr>
<td></td>
<td>Supports Duke University with proposal and budget development. Budget development is supported by automatic calculation of fringe benefits, indirect costs, inflation adjustments and modular grant offsets for NIG proposals.</td>
<td>For Campus, contact ORS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For SOM &amp; SON, contact ORA</td>
</tr>
<tr>
<td><strong>PROPOSAL &amp; BUDGET SUBMISSION</strong></td>
<td>Sponsored Projects System (SPS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The proposal routing system used by Duke University for tracking departmental and central office review and approval of grant submissions.</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Grants.duke</td>
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</tr>
<tr>
<td></td>
<td>A website that ties the SPS to the federal Grants.Gov system, allowing a system-to-system submission of NIH, DOE and many DOD proposals.</td>
<td><a href="https://grants.duke.edu/">https://grants.duke.edu/</a></td>
</tr>
<tr>
<td><strong>AWARD &amp; PROJECT SET UP</strong></td>
<td>SAP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application used for University and Health System core administrative processes, including accounting, human resources, payroll, purchasing financials, ordering materials and paying employees. SAP is used at award set up to verify “master data” via CJ03 transaction and verifying awarded budget entry into the system by using the ZFR1E transaction.</td>
<td>To gain access to SAP, contact your system administrator within your department/unit.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For more information, visit: <a href="http://finance.duke.edu/systems/sap/signup.php">http://finance.duke.edu/systems/sap/signup.php</a></td>
</tr>
<tr>
<td></td>
<td>Sponsored Effort System (SES)</td>
<td></td>
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<tr>
<td></td>
<td>Allows central grant offices to update awarded effort information and allows departmental users to view active and pending effort for personnel supported on grant funds. SES is used at the Award &amp; Project Set Up stage to review effort commitments for personnel supported on sponsored projects. For updates needed in the system for SOM.SON employees, contact your pre-award office.</td>
<td>To gain access to SES, contact your Pre-Award Office.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For Campus, contact ORS</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>LIFE CYCLE STAGE</td>
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<tr>
<td>-----------------</td>
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</tr>
<tr>
<td>AWARD &amp; PROJECT MANAGEMENT</td>
<td>SAP</td>
<td>To gain access to SAP, contact your system administrator within your department/unit. For more information, visit: <a href="http://finance.duke.edu/systems/sap/signup.php">http://finance.duke.edu/systems/sap/signup.php</a></td>
</tr>
<tr>
<td></td>
<td>Duke@Work Online Portal</td>
<td>Everyone should have access to <a href="http://finance.duke.edu/systems/sap/signup.php">Duke@work</a>. If you need help, contact your designated SAP administration with your department/unit.</td>
</tr>
<tr>
<td></td>
<td>Grant Management Tab (via Duke@work Portal)</td>
<td>Users should request access to the Grants Management tab via their SAP Security Administrator.</td>
</tr>
<tr>
<td></td>
<td>Universal Worklist</td>
<td>The Universal Worklist is a tab that can be found in <a href="http://finance.duke.edu/systems/sap/signup.php">Duke@work</a>. If you need help, contact your designated SAP Administrator with our department/unit.</td>
</tr>
</tbody>
</table>

SAP Application used for University & Healthy System core administrative processes, including accounting, human resources, payroll, purchasing, financials, ordering materials and paying employees. SAP is used during the life of Award Management to review expenses and verify activity using various SAP transactions.

Duke@Work Online Portal
A website that supports faculty and staff in sponsored research administration and acts as the key point of entry to access your Universal Worklist, the Effort Certification Reporting Technology (ECRT) Management System, Grants Management Tab and Buy@Duke.

Grant Management Tab (via Duke@work Portal)
This is a primary resource for research administrators in their support of Sponsored Research Administration (SRA). This tab provides various reports and functional tools that are specific to sponsored research. The Grant Management tab includes many daily tools needed for a research administrator at Duke.

Universal Worklist
The online inbox for reviewing and approving various transactions related to the spending of award funds on the projects in which you are assigned as a research administrator.
<table>
<thead>
<tr>
<th>LIFE CYCLE STAGE</th>
<th>SYSTEM</th>
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</tr>
</thead>
<tbody>
<tr>
<td>AWARD &amp; PROJECT MANAGEMENT</td>
<td><strong>Effort Certification &amp; Reporting Technology (ECRT)</strong>&lt;br&gt;A web-based system that serves as the institution’s effort reporting and certification tool for personnel paid on sponsored research projects. Each department will have two groups of ECRT users:&lt;br&gt;Effort Coordinators, who are responsible for the final review and processing of completed effort statements.&lt;br&gt;Certifiers (faculty and exempt staff) who are responsible for certifying their effort.</td>
<td>Questions regarding ECRT should be directed to ECRT-Support via email at <a href="mailto:ecrt_support@duke.edu">ecrt_support@duke.edu</a>.</td>
</tr>
<tr>
<td>AWARD &amp; PROJECT END</td>
<td><strong>Buy@Duke</strong>&lt;br&gt;Duke’s web-based e-procurement tool to procure goods and services supporting business at Duke.</td>
<td>Contact the Procurement Office (<a href="mailto:procurement@duke.edu">procurement@duke.edu</a>) for assistance with issues related to.</td>
</tr>
</tbody>
</table>
UPDATE

AGM
New Program beginning in February. RCC will inform applicants tomorrow (January 27th) as to acceptance and class dates, starting in February 10th.

Continuing Education
Remember, continuing education is changing to credit hours to accommodate dedicated hours of learning as of July 1, 2017. Discussions underway to count external webinars. Also, RCC will be contacting individuals who presented sessions at the Symposium for interest in repeating these as continuing education opportunities for those who couldn’t attend a specific session.

Mandatory Evaluations
Remember, evaluations for all RCC courses will begin as of July 1, 2017. Although these are currently optional, we appreciate feedback and encourage you to become accustomed to completing the evaluations now, as they will be mandatory for credit as of July 1, 2017.

RCC Alert
Supplemental information to communicate new items, information; The Grant Management Community News will continue as an every other month more detailed newsletter.
Scheduled to launch in Spring 2017, QuickStart is developed to provide grant management “onboarding” to new employees within the first 90 days of hire and current Duke employees not in the RACI HR classified positions for grant management, but are performing limited research management functions.

**Program Details:**
- Six on-demand, self-paced online training modules with references and step-by-step guides
- *Capstone Class* that provides “hands-on” experience in a limited number of basic grant activities
- Enables new grant managers to learn basic research management concepts and skills in advance of entering RAA
- Supports individuals who perform basic grant duties, but are not currently eligible for RAA

RCC is excited to announce a **completely revised** AGM curriculum scheduled to begin in **February 2017**! AGM enrollment is now open and we are accepting applications.

The AGM Program consists of five **required** courses and a final exam.

**AGM Program Courses will include:**
- Advanced Effort Management
- Case Studies in the Federal Regulatory Environment
- Complex Project Management: Pre-Award
- Complex Project Management: Post-Award
- Communication Strategies in Research Administration

RCC has added a new class for continuing education or as RAA Elective beginning in April 2017.

**Class:** Fellowship, Training & Career Awards

**Details:** Features best practices for management these types of award on both the pre and post-award side.

**NOTE:** If you have previously taken “Management of Training and Career Awards,” this class offers additional information on fellowship applications and awards.

**Click here to register in the LMS!**

*AGM NOTE: RCC hopes to offer each of the AGM classes three times a year to accommodate certification requirements. These new classes may be used toward continuing education credit for anyone who holds a current AGM certification. Course descriptions and scheduling information can be found in LMS.*
Questions?

Please contact rcc-cert@duke.edu
ClinicalTrials.gov Updates: NIH Policy

January 2017
DOCR’s Role

- **Provide Support**
  - System administrator for Duke since 2012
  - Assist with trial registration, results entry, and resolution of QA comments from ClinicalTrials.gov

- **Offer Training**
  - Introduction class and results entry workshop
  - Web-based Introduction class in 2017

- **Monitor Compliance**
  - Registration: review all new studies and manage approval for ACTs and qualifying trials
  - Results: track results due date based on dates provided by study team; send reminders to PI and regulatory staff

- **Share Best Practices with CTSA Partners**
  - REDCap tool; policies; resource allocation
Overview of Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective date</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable Clinical Trial (FDA-regulated products)</td>
<td>FDAAA: 2007 Final Rule: 1/18/2017</td>
<td>Registration &amp; results</td>
</tr>
<tr>
<td>Qualifying trial (billing insurance)</td>
<td>2015</td>
<td>Registration</td>
</tr>
<tr>
<td>ICMJE clinical trial (publication)</td>
<td>2005</td>
<td>Registration</td>
</tr>
<tr>
<td>NIH-funded clinical trials <em>New</em></td>
<td>1/18/2017</td>
<td>Registration &amp; results</td>
</tr>
</tbody>
</table>
Final NIH Policy

All NIH-funded clinical trials must be registered and have results reported in ClinicalTrials.gov

• NIH definition of “clinical trial” (all clinical trials, regardless of study phase or type of intervention)
• Grants, contracts submitted on or after the effective date
• Competing renewals that include a clinical trial initiated on or after the effective date

Effective Date: January 18, 2017
NIH Policy Highlights

• Follow the same requirements and timelines as outlined in the regulations
  • Registration: Institutional approval will be held until the study is registered
  • Results: Due within one year of the Primary Completion Date
• As part of the application or proposal, submit a plan for how the expectations of the policy will be met
• Include a statement in the consent form
Final Rule: Key Changes
(apply to ACTs and NIH-funded trials)

- Full protocol and statistical analysis plan must be submitted and will be made public
- Defined deadlines for
  - Updates to registration information
  - Resolution of quality control comments from ClinicalTrials.gov
  - Results entry for secondary outcome measures
Consequences of Noncompliance

• Suspension or termination of funding
• Can be considered in future funding decisions (for the grantee institution)
• Identifying clinical trial record as non-compliant in ClinicalTrials.gov
Workflow at Duke

**Registration**
- ACTs, NIH-funded clinical trials, and trials billing insurance are registered prior to DOCR approval in eIRB

**Maintenance**
- Monthly reports regarding outstanding items/errors

**Results Entry**
- Reminders prior to due date at 12, 6, 3, 2, and 1 months
- Defined escalation procedure
Questions?

DOCR-CTgov@dm.duke.edu

Jessica Houlihan
Kristy Astin
Rebekah Davis
Jennifer Griffith
Susan Natoli
GCP Training for NIH Funded Studies Update

Lorna N. Dula
Associate Director, Research Operations
DOCR Training and Communications
New Policy National Institutes of Health (NIH)

• Issued on September 16, 2016
  • NIH-funded investigators and staff should be trained in Good Clinical Practice (GCP) effective January 1, 2017.
  • This policy applies to all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical research.
  • Grace period extended till March 2, 2017

• CITI Program GCP courses meet the NIH Policy requirements
  • Meet the minimum criteria for ICH GCP Investigator Training identified by TransCelerate BioPharma.
NIH GCP Status Update

• **Status as of January 22, 2017:** Completion data tracked indicates that we are overall 46% complete.
  
  • Completion of GCP Course = **completion of all modules of approved courses in CITI**
    
    • Total KP on NIH funded has changed over time as KP lists are modified
    • KP have been identified as having completed relevant training at other facilities
    • RPMs and DOCR communicating with staff and faculty
Challenges

Users have expressed dissatisfaction with taking the GCP modules
- Number of modules intimidating to some
- Hours of time to complete – several hours
- Accessing the modules difficult (we are restricted due to CITI program)
- Nature of CITI modules - all text - cumbersome

Administrative challenges maintaining update list due to:
- Ongoing removal of Key personnel from protocols
- Issue with CITI push for some members at refresher stage completion 3 and 4

GCP Training from other institutions accepted if Trancelerate approved

*Overall everyone has communicated and has been cooperative*
## Next Steps - Path Forward

<table>
<thead>
<tr>
<th>Task</th>
<th>Date started</th>
<th>Target Date Completion</th>
<th>Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase frequency of updates to CRUs</td>
<td>1/9/2017</td>
<td>2/28/2017</td>
<td>DOCR</td>
</tr>
<tr>
<td>Contact individuals (KP) needing GCP</td>
<td>1/23/2017</td>
<td>1/23/2017</td>
<td>RPMs</td>
</tr>
<tr>
<td>CITI merge GCP and Biomedical Research - stand alone + Biomedical Research (admin task)</td>
<td>2/15/2017</td>
<td></td>
<td>DOCR/CITI</td>
</tr>
<tr>
<td>Obtain Administrative rights for DCRI and University Domains for tracking</td>
<td>2/1/2017</td>
<td></td>
<td>DOCR</td>
</tr>
<tr>
<td>Interface to LMS for transcript completion</td>
<td>2/1/2017</td>
<td></td>
<td>CITI/DOCR</td>
</tr>
<tr>
<td>Activate CITI Course change title – remove Basic Biomedical merge - admin task for uploading</td>
<td>2/28/17</td>
<td></td>
<td>CITI/DOCR</td>
</tr>
<tr>
<td>Duke Health researchers who are not on NIH studies will be required to take the CITI GCP module or renewal when current credentialing expires.</td>
<td>Ongoing</td>
<td>Ongoing</td>
<td>DOCR</td>
</tr>
</tbody>
</table>
Key Points

• International research definition
• Big ticket issues to keep in mind
• Special budget considerations
• Managing the post-award environment
• Communicating effectively with collaborators
• Q&A
What is International Sponsored Research?

No simple definition

• Example: What if Duke PI travels internationally?
  • Is a conference in Switzerland the same as working in Kenya year-round?
• MOST research Duke does have some international component, however indirect

The reason that “international” matters is that it often brings complexity to a proposal/project

• Many issues faced in the international space are rarely seen on the domestic side

So what should you look for in a proposal?
<table>
<thead>
<tr>
<th>Does the proposal include?</th>
<th>Why this matters</th>
<th>Other issues to consider</th>
</tr>
</thead>
</table>
| Duke faculty/staff working at an international location ("boots on the ground")         | 1. Hiring local staff  
2. HR, Tax, Legal requirements  
3. Banking/payments                                                                 | 1. Length of stay (2 weeks versus 8 months)  
2. Number of staff  
3. Duke vs Non-Duke people  
| Sponsor (or Prime) is an international entity                                             | 1. Foreign legal requirements  
2. Agreement issues                                                                     | 1. Translation needed?  
2. Might need Legal to weigh in                                                           |
| Human Subjects work and/or work with animals will be done outside the USA by Duke       | 1. Campus and SoM IRB are expert on US rules but not expert on the rules in all other countries | 1. Will data (HS or otherwise) be sent back to USA?                                         |
| Human Subjects work and/or work with animals will be done outside the USA by a third party (e.g., subawardee) | 1. Duke must get IRB approval even if no Duke personnel engaged in HS  
2. Some local partners may not have an IRB                                               | 1. Will data (HS or otherwise) be sent back to USA?                                         |
<table>
<thead>
<tr>
<th>Does the proposal include?</th>
<th>Why this matters</th>
<th>Other issues to consider</th>
</tr>
</thead>
</table>
| Subawardees are international entities                          | 1. If federal work, subs may need DUNS, SAM.gov, etc.  
2. Some smaller subs may lack experience and need help budgeting, etc.                                                                                   | 1. Has PI assessed whether sub has capacity to do the work (Technical? Financial?)                           |
| Duke is sending data or items/goods to international destination | 1. Different rules on data privacy and security (EU)                                                                                                                                                            |                                                                                                                                                                  |
| Duke is bringing tangible items from foreign site into USA     | 1. Could have customs issues  
2. Animals/animal products                                                                                                                                             |                                                                                                                                                                  |
| Project involves foreign nationals coming to USA/Duke          | 1. Exposes Duke to liability  
2. Foreign visitors may need help with visas, insurance, etc.                                                                                                                                                  | 1. What is the nature of the visit?  
Lab work vs training course?  
2. Short or long-term?  
3. In-country logistics                                                                                                           |
How Can I Help?

• Make sure you always fill in the international sections of your SPS records

• Let your representative know as early in the process as you can – well before the proposal is routed – that your PI is planning on submitting an international proposal

• Make sure your PI is thinking about all international – related budget items
  • Security, tax, insurance, etc.
Budgets

• Big-ticket issues to keep in mind when putting together an International Research proposal
• Special considerations that should be factored into the budget preparation process when conducting International Research
• Practices for effectively managing and minimizing turmoil in the post-award environment – both in terms of project management and financial management
Big-ticket Issues for Budgets

- Build enough time into the preparation process, in light of different time zones
- Factor in time to explain (to new sub-recipients) the process of getting DUNS numbers, FWA assurance, Animal Welfare Assurance, etc.
- Try to conceptualize the budget in terms of whether the costs should be part of Duke’s budget or the budget of a sub-recipient
- How can the work best be accomplished by collaborators
- On-Campus vs. Off-Campus F&A rate
Special Considerations

• Duke costs or Sub-Contract/Award Costs?
  • Duke costs? If research is taking place in an off-campus environment over longer periods of time:
    • Pay for off-campus rent for facility?
    • Other costs – Electricity, Security, Telecommunications, Vehicle, Vehicle Maintenance?
  • Sub Costs
    • Make sure sub is building budget that is appropriate to the work that will take place
    • F&A Rate Agreement? If no, consider direct costing administrative items
    • Build wire fees into Duke budget to support the sending of wires to international partners

• Other Items to include in Duke budget
  • Audit?
  • Medivac/DBA Insurance when spending time out of the country?
  • Visa Costs
  • Try to think out all of the potential cost elements to carry out research
Practices for Post-Award Management

- Make sure budget set up in proposal process has thought through the post-award environment
- Contracts vs. Sub-contracts
  - Contracts – International RSSA vs. A/P Check Request
  - Sub-Contracts – required reporting and payment options
- Financial Reports for Sponsors
  - Sometimes the Grant Administrator and Program Team need to help OSP/TBS with financial reporting
  - Collecting revenue from certain foreign sponsors difficult sometimes
- Other items
  - Audit Risk for Subs ➔ Collect all of the original receipts/documentation as possible
  - Fly America and Open Skies Agreement
  - Consider using International Per Diem when traveling, due to difficulty with collecting itemized receipts ➔ Consider modified per diem
  - Be careful buying meals for collaborators when abroad, due to problems with reimbursement
What Should I Do?

• Let your RA/RAM/AD know
  • Important that your ORS/ORA representative is aware
  • RA/RAM/AD will contact me when needed

• Depending on the complexity of any particular international proposal:
  • I may serve as your ORS/ORA representative for the proposal;
  • I may work in tandem with your ORS/ORA representative (your representative will remain primary contact); or
  • Your ORS/ORA representative may handle the proposal, with me providing assistance to your representative as needed
ORA News and Reminders
Total Professional Effort (TPE) Reminder

- Statement regarding TPE must be included in ALL applications including Faculty <50% Duke appointment
- Calculator on ORA website
  - Auto calculates TPE %
  - Includes standard verbiage
Dr. Grant holds both university and non-university appointments. The commitment of 2.4 calendar months of university appointment to this project represents 8%, or 0.96 calendar months of total professional effort.
Employee Salary Request Form

- Dept. submitting the application is responsible for including TPE statement for all faculty with <50% appointments, regardless of PI’s owning ORG
- Depts. need to communicate via Employee Salary Request Form if appointment is <50%
- [https://medschool.duke.edu/sites/medschool.duke.edu/files/field/attachments/Salary_Request_Form.pdf](https://medschool.duke.edu/sites/medschool.duke.edu/files/field/attachments/Salary_Request_Form.pdf)

Employee Salary Request
(see next page for instructions)

- Specify whether the individual has a Duke SOM appointment of less than 50% in the Salary Notes.
Personal Services Agreement (PSA)

- Revised “Duke as a Sponsor” and “Institute for Medical Research (IMR) as a Sponsor” forms
- Please use for all new, modified or extended PSAs
- [https://medschool.duke.edu/research/research-support-offices/office-research-administration/va-partnerships/veterans-affairs-psas](https://medschool.duke.edu/research/research-support-offices/office-research-administration/va-partnerships/veterans-affairs-psas).

Personal Services Agreement

**Part I – Nature of the Service Agreement**
- [ ] New Agreement
- [ ] Modification
- [ ] Extension

**Part II – Information on Participating Employee**

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>2. Name (Last, First Middle)</td>
<td>3. Social Security Number:</td>
</tr>
<tr>
<td>4. Home Address (Street, City, State, ZIP)</td>
<td></td>
</tr>
</tbody>
</table>
• ORA includes Foundation Exception Letter with applications to sponsors who require Duke to sign off on terms and conditions with applications
• Typically non-profit sponsors
• Critical for maintaining Duke’s ability to negotiate and accept the award
• Please be sure to include this letter in the application if the department is submitting the application

January 19, 2017

To AANEM Foundation for Research & Education:

On behalf of Duke University, I am pleased to endorse the enclosed proposal submitted by [PI Name] titled [project title]. We have reviewed the proposal, and if the proposal is funded, we agree to administer the resulting award.

Please note that Duke University only conducts basic and applied research in science and engineering, the results of which are published and shared broadly within the scientific community. Final determination of what may be published or not published must remain with the university. Duke University cannot accept award terms which would violate our fundamental research status nor can we accept terms which would violate our University-Industry Guidelines, a copy of which is available at: [http://provost.duke.edu/wp-content/uploads/FHRI_App_P.pdf](http://provost.duke.edu/wp-content/uploads/FHRI_App_P.pdf).

Duke University reserves the right to negotiate agreement terms if awarded.

We look forward to this collaboration between our organizations.

Sincerely,

[Signing Official]
Duke University School of Medicine
Office of Research Administration
2200 West Main Street
Box 304005, Suite 620 Erwin Square
Durham, North Carolina 27705
Accounts Clean-up

- SPS Security Officer/eRA Commons AOs in departments are responsible for setting up SPS and eRA Commons accounts
- Department’s responsibility to keep accounts up to date
- We’re finding many old accounts still active in both systems
- ORA recommends annual review
ORA Signatures

- eRA Commons’ Signing Officials have authority to submit prior approval and other official documents to GMS at NIH
- The ‘Duke way’ has been to include Director/Associate Director signature block on these
- If the SO is sending the request via email or eRA Commons to NIH, no additional signature is necessary
Prior Approval for Fixed Price Subawards

• § 200.332 Fixed amount subawards require prior written approval from agency

• NIH is the only agency that provided a waiver to the requirement in an FAQ in Feb. 2015

• Updated NIH GPS (Oct. 2016) 8.1.2.11 now requires prior approval on NIH awards for fixed price subawards. Applies retroactively to grants with a budget period starting on or after October 1, 2016.

• COGR is asking for clarification, but as of Oct. 1, 2016, any fixed price subawards will need to have prior approval for each entity. At proposal stage, you can budget and make clear in the justification that it will be fixed price and that will be considered approval if awarded. Prior approval is not provided if you list the subs as TBD or fail to include language that your intent is to issue them as fixed price.
NIH application guide and supplemental instructions

• NOT-OD-17-023

• Minor changes to the layout and style of instructions

• New instructions are marked with this symbol 🚨
  • Hover over the icon in the web version to read an explanation of the change
  • The symbol will be visible in the PDF version, but will not display hover text

• Significant changes can be read here:
  https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.120-significant-changes.htm
How to Use the Application Instructions

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.100-how-to-use-the-application-instructions.htm
... and NSF PAPPG Proposal & Award Policies & Procedures Guide


• Effective for proposals submitted or due, and awards made on or after, January 30, 2017
  • NSF Grants.gov application guide -
  • Frequently Asked Questions (FAQs) On Proposal Preparation and Award Administration -
  • NSF Award Terms and Conditions -
PCORI – New Version PCORI Online

• Progress Reports must be submitted via PCORI Online effective Jan. 2\textsuperscript{nd}
• All PCORI funding opportunities for Cycle 1 2017 onward will utilize the new PCORI Online including:
  • Submitting LOIs
  • Applications
  • PCORI Information Requests
• Applications being submitted for Cycle 3 2016 Funding Opportunities will not utilize the new PCORI Online
• User manual and recorded webinar training course that you will be able to access via PCORI.org coming soon!
• \url{http://www.pcori.org/funding-opportunities/awardee-resources}
NIH Implementation of Final Research Performance Progress Report (Final RPPR)

- NOT-OD-17-022
- Effective January 1, 2017
- The Final Research Performance Progress Report (F-RPPR) replaced the Final Progress Report (FPR) for grants closeout
NIH Implementation of Final Research Performance Progress Report (Final RPPR)

- The format of the F-RPPR is very similar to that of the annual RPPR
- **Removed** sections F (Changes), and H (Budget)
- **Added** Section I (Outcomes)
  - Project Outcomes (Section I) will be made publicly available, allowing recipients the opportunity to provide the general public with a concise summary of the public significance of the research
The F-RPPR, in an ideal world...

**STEP 1:** Grant Manager (GM) engages with PI to review the PI’s role in the financial closing out of the award, such as the importance of following deadlines when submitting the F-RPPR & signing the PI Attestation.

1. GM engages with PI
2. PI works on final report
3. GM communicates name of ORA rep. for eRA Commons

**STEP 2:** PI begins to work on the F-RPPR while GM works on financially closing out the award (through the close out process, e.g. 60 days)

**STEP 3:** GM engages with PI for status updates including the F-RPPR & shares the name of the appropriate ORA representative for eRA Commons;

GM also communicates any exceptions to the process to ORA.
**STEP 4:** PI selects ORA representative (dept. rep, not John or Michael) & routes; eRA Commons sends automated email to official to review

**NOTE:** No new SPS record or Admin Action Request is needed

**STEP 5:** ORA provides (minimal) review within 2 Duke business days

**STEP 6:** ORA submits the Final RPPR prior to day 90 (closeout)

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The F-RPPR, in an ideal world...
Validate each section for errors

Please remember to run validations and correct all errors prior to routing to ORA
NIH Implementation of the Interim-RPPR while a Renewal Application is Under Consideration

- NIH NOT-OD-17-037
- Effective Feb. 9\textsuperscript{th}
- Interim-RPPR utilized when competing renewals are submitted
- NIH will discontinue the policy for renewal applications whereby, “whether funded or not,” the progress report contained in the renewal application may serve in lieu of a separate final progress report
- An Interim-RPPR link for the grant will appear in the Status tab in eRA Commons after the period of performance end date has passed
NIH Implementation of the Interim-RPPR while a Renewal Application is Under Consideration

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Status of Competing Renewal Application</th>
<th>Workflow Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Competing Renewal not submitted</td>
<td>Submit a Final-RPPR no later than 120 calendar days from the period of performance end date.</td>
</tr>
<tr>
<td>2</td>
<td>Competing Renewal submitted</td>
<td>Submit an Interim-RPPR no later than 120 calendar days from the period of performance end date. If the competing renewal is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.</td>
</tr>
<tr>
<td>3</td>
<td>Competing Renewal submitted but not funded</td>
<td>Submit an Interim-RPPR no later than 120 calendar days from the period of performance end date. If the competing renewal is not funded, NIH will treat the Interim-RPPR as the institution's Final-RPPR. To reduce burden NIH will not require recipients to submit an additional Final-RPPR if the renewal application is not funded.</td>
</tr>
</tbody>
</table>
NIH & AHRQ Update Font Guidelines

• NOT-OD-17-030

• **Text Color:** No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

• **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.

• **No restriction on font type** – though there are recommendations (Arial, Georgia, Helvetica, Palatino Linotype)
During an NIH NCE, is there a minimum effort requirement for key personnel named in the NOA, other than the PI?
NIH NCE Effort Requirement

• NIH GPS 8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds
  • NIH will not require prior approval for the reduction in effort for Senior/Key personnel named in the NOA. The recipient is reminded that active awards must have a measurable level of effort.

• NIH GPS 8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA
  • The recipient is required to submit a prior approval request to the GMO if the PD/PI or other Senior/Key Personnel specifically named in the NoA will:
    • Withdraw from the project entirely
    • Be absent from the project during any continuous period of 3 months or more
    • Reduce time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award
During a No-cost Extension, Is There a Minimum Effort Requirement for Key Personnel Named in the Notice of Award, Other than the PI?

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 named in the Notice of Award (NoA) during a no-cost extension. However, consistent with the NIH Grants Policy Statement Chapter 8.1.1.3, recipients are reminded that for active NIH awards, the PD/PI and other Senior/key personnel named in the NoA must devote a measurable level of effort.
Should vs. Must
Proposal Review Criteria

Documents To Print

Prepare Performance Metric Form after review (Print on Yellow Paper).
Print SPS Web review copy and DPAF (non-signature pages).
Print all internal documents.
Print Solicitation/Guidelines/Instructions for this proposal.
Print Grants.Duke application or Adobe Package (if unable to submit through SPS).

DPAF (page 1,2,3)

- Items for Review
  - Is the Proposal Type marked as NEW? [ ] [ ] [ ]
  - Is the F&A rate correct? Note the primary project location [ ] [ ] [ ]
Guidelines and Policy

MIGHT SHOULD
Recommendations based on experience/guidelines

MUST
Requirements based on Duke/Sponsor policy
Recommendations based on experience/guidelines

Less Risk

More Risk

Might Should

Award

MUST
Requirements based on Duke/Sponsor policy
That Escalated Quickly!
• Consultant vs. Sub

We Need to Talk
• Changes in scope

I’m Not Mad, Just Disappointed
• Cost Share

It’s All Fun and Games...
• Personnel Roles

LESS RISK

MORE RISK

Proposal

Award

It Depends Matrix!
ORA/Dept.
Relationship Status Matrix

MIGHT SHOULD
Recommendations based on experience/guidelines

MUST
Requirements based on Duke/Sponsor policy

LESS RISK

MORE RISK

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• Personnel Roles
Awards
The ‘Time’ is Right
Earliest Feb. 5\(^{th}\) Submission

- Earliest submission for R01 10/5 Deadline
- Date stamped from grants.duke

- None... so far

Earliest Nov. 5\(^{th}\) Submission

- Neurobiology
  - 10/28/16 @ 10:45AM
  - Dr. Stephen Lisberger
  - PAL: Cristy L. McGranahan
Can’t Can Make it On Time

• FY17 Quarter 2
• No Waivers
• Minimum 5 Submissions
• Immunology
  • 100% On-Time
Distinguished J.M. Teamwork Award

• Recognizes department for their outstanding commitment to teamwork
• Award seeks to perpetuate the excellence of collaboration and support between central and department offices by recognizing and honoring qualities such as:
  • Generosity
  • Giving
  • …and incredible omelettes
• Otherwise known as the best attempt to bribe ORA!
• Psychiatry
  • Making us homemade breakfast never hurt anyone!
Professional Development and Training Update
Upcoming Training Opportunities - Conferences

• SRA NC Chapter Meeting
  • Winston-Salem, NC; March 17, 2017

• NCURA Region III
  • Savannah, GA; May 6-10, 2017

• SRA Southern/Midwest Section
  • Nashville, TN; May 7-10, 2017

• NIH Seminar
  • Chicago, IL; May, 2017
Research Performance Progress Report (RPPRs) for NIH

NIH Application Development, Management & Resources – The FOA – Part 1 of 2

NIH Application Development, Management & Resources – The FOA – Part 2 of 2

NIH Application Development, Management & Resources – Building Your Basic Budget Part 1 of 2

NIH Application Development, Management & Resources – Building Your Basic Budget Part 2 of 2

NIH Application Development, Management & Resources – It’s Just In Time & the Notice of Award

Tuesday, January 31

Tuesday, March 7

Tuesday, March 21

Tuesday, April 18

Tuesday, April 25

Tuesday, May 16
Sponsored Projects System (SPS): A Hands On Training  
Friday, May 26

Other Support, Primarily for NIH  
Wednesday, June 7

NIH Research Performance Progress Reports (RPPRs)  
Friday, June 16

Intergovernmental Personnel Act (IPA) & the VA  
Wednesday, June 28

Memorandums of Understanding (MOUs) & Personal Service Agreements (PSAs) for the VA  
Wednesday, July 12

eSubmissions  
Wednesday, July 26
ORA Staff Update
ORA Personnel Update

• Arrivals
  • n/a

• Openings
  • Research Administration Manager – Grants
  • Research Administration Manager – Grants Management Team (of 1)
  • Research Administration Manager - International
  • Research Administrator

• Departures
  • John DeFore
  • Latesha Williams
LMS Registration & Credit

• If you are not on the roster &/or signed up less than 2 business days prior to our meeting, give us 2 business days to add you to the system (remember to sign in legibly & with Net ID)

• Those who did not sign in will be listed as ‘no shows’ in LMS within 3 business days
To receive credit, each person who signed in will be sent a Qualtrics “By Invitation Only” link.

This link can be only be used once per person (Qualtrics records your information).

Please put some thought into your responses – we need your input.

Note: The credit should be listed in LMS within 14 days after survey is completed.