Agenda

Export Controls – Dan Vick & Terrence Rusch
Closeout Update – Implementation Team
RSSA Update – Dean Freck
Policy Update – Jim Luther
Basics of Human Research – Jennifer McCallister, David Matesanz, Susan Hayden, Curt Bradney
ORA Update – Michael Dickman
ORA Personnel Update

• Arrivals
  • Research Administrator – Taylor Filippini
  • Research Administrator – Brooks Fuqua
  • Research Administration Manager – Dana Hewitt
  • Research Administration Manager – Christina Jackson

• Departures
  • Danielle Robinson

• Openings
  • Research Administration Manager - International
  • Research Administrator
  • Research Administrator
ORA Org Chart
ORA Customer Service Survey Results
Approach

• Targeted department grant managers (28)
• General feeling regarding effectiveness of ORA
• Highlighted pre-award, award management, and electronic support
Responses

Grant Managers

- 39% Response
- 61% No Response
Has Pre-Award improved over the last year?

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<th>Agree</th>
<th>No Change</th>
<th>Dissagree</th>
<th>Strongly Dissagree</th>
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<tr>
<td>Professionalism</td>
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Results - Award Management

Has **Award Management** improved over the last year?

<table>
<thead>
<tr>
<th>Category</th>
<th>Strongly Agree</th>
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<th>No Change</th>
<th>Dissagree</th>
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<td>Professionalism</td>
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</table>
Results - Electronic Tools

Electronic Tools

- SPS: Very Satisfied
- Grants.duke: Satisfied
- Sponsor Effort: Dissatisfied
- Admin Action Request: Very Dissatisfied

Scale: 0-10
Results - Website

Website

Navigation  Tools  Education and Training  General Content

Very Satisfied  Satisfied  Dissatisfied  Very Dissatisfied

0  2  4  6  8  10  12  14
ORA News and Reminders
Contacts Us

Office: Erwin Square Plaza
Suite 820
Mailing Address: Duke University
Box 104008
Durham, NC 27710
Telephone: 919-684-5157
Email: gcmail@mc.duke.edu
Hours: 8:00AM – 5:00PM

https://medschool.duke.edu/research/research-support-offices/office-research-administration/about-ora/ora-contact-us

https://medschool.duke.edu/research/research-support-offices/office-research-administration/about-ora/ora-assignments
ORA Contacts for RSSA’s

- RSSA first routes to central contacts within ORA
- ORA central contacts route the RSSA to ORA representative
- Lab staff often contact central ORA contacts to expedite the RSSA
- In an ideal world:
  - Lab staff should reach out to department grant support for assistance
  - If ORA is needed, department grant support reach out to ORA representative
  - Please allow at least 3 business days before reaching out
Contracts Team to ORC

- Effective 11/1/16
- Contracts team transitioned to ORC
Contacts in ORC

https://medschool.duke.edu/research/research-support-offices/office-research-contracts/contact-us

- Federal Contracts and federal grants, foundation/non-profit grants, and state contracts –
  - Pre-award for federal contracts
  - Agreement negotiation and ORC signature
  - Issuing subs
  - Budget changes at contracting stage
  - Awarding in SPS
  - Training sessions and/or programs if or when applicable

- Continue to send federal and foundation agreements to Contracts Management (contracts.management@mc.duke.edu)
Investigators with joint appointments at a VAMC (VA hospital) and an affiliated university must have a valid MOU that specifies (at both the university and the VAMC) the title of the investigator's appointment, distribution of compensation, the responsibilities of the proposed investigator, and the percentage of effort available for research at each institution.

The MOU must be signed by the appropriate officials of the recipient and the VAMC, and must be updated with each significant change of the investigator's responsibilities or distribution of effort and, without a significant change, not less than annually.

The joint VA/university appointment of the investigator constitutes 100 percent of his or her total professional responsibilities. However, NIH will recognize such a joint appointment only when a university and an affiliated VA hospital are the parties involved.
NIH MOU Requirements (cont.)

The signature of the AOR of the submitting university on an application to NIH that includes such an arrangement certifies that:

- The individual whose salary is included in the application serves under a joint appointment documented in a formal MOU between the university and the VA, and
- There is no possibility of dual compensation for the same work or of an actual or apparent conflict of interest
What is the Duke process?

• Effective June 1, 2017

• When dual appointment exists:
  • Valid MOU is required to submit an application to NIH (this is a must)
  • Dept. required to attach fully executed MOU in SPS internal docs
  • ORA will return applications that do not include an MOU

• If an MOU cannot be presented at submission time, then:
  • ORA will assume there is no Duke IBS and measurable effort cannot be documented
  • The individual cannot be listed as the PI or Senior/Key personnel
SPS – Attaching FOA in Internal Docs

- Solicitation number required in SPS for NIH applications
- Attaching FOA is no longer required for NIH applications only
- FOA must be attached for all non-NIH applications
- SPS record will be returned if:
  - NIH solicitation # is not included for NIH applications
  - FOA not attached for all non-NIH applications (exception noted above)
- Exceptions (kind of):
  - When Duke is a sub include documentation of what sponsor requires (e.g. email, prime FOA)
  - No FOA? Document sponsor does not have FOA in proposal memo
Return for Changes (RFC)
Request for Collaboration (RFC)
Request for Collaboration (RFC)

- Mechanism that allows the department to make changes in SPS
- No longer used for department scorecards
- Tool to communicate what changes need to be made
- Requests range from might should to must
- Record of ORA ‘must requests’ and changes to the SPS record
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

MIGHT SHOULD
Recommendations based on experience/guidelines

MUST
Requirements based on Duke/Sponsor policy

Proposal

Award

ORA/Dept. Relationship Status Matrix
• Departments request RFC reports and want to compare to baseline
• Feedback is that ORA is inconsistent
  • Changes range from might should to must
  • ORA not returning for might should suggestions
  • Depts request ORA to make changes in SPS for department instead of RFC
• ORA training to return records consistently
  • Return SPS records for must changes
  • Return SPS records rather than make changes for depts
RPPR – Other Support

RPPR Instruction Guide

D.2.c Changes in other support.

Has there been a change in the active other support of senior/key personnel since the last reporting period?

If yes, upload active other support for senior/key personnel whose support has changed and indicate what the change has been. List the award for which the progress report is being submitted and include the effort that will be devoted in the next reporting period.
RPPR – Other Support (cont.)

• What constitutes a change?
  • Previously active grant has terminated
  • Previously pending grant is now active

• Submission of other support information is not necessary if:
  • Senior/Key personnel is considered an Other Significant Contributor
  • Support is pending
  • Changes in the level of effort for active support reported previously
  • Note: Changes in effort requiring prior approval still need to be addressed
RPPR – Other Support (cont.)

• What constitutes senior/key personnel? Sponsor vs Duke key?
  • Individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not a salary is requested
  • PD/PI and for those individuals considered by the grantee to be key to the project

• Who is the ‘grantee’ that determines who is key?
  • The PD/PI
The PD/PI would like to designate in the application all personnel as senior/key. Should we do so?

No. Keep in mind the term “senior/key” applies only to individuals who contribute to the scientific development or execution of a project both substantively and measurably. If you misidentify personnel as senior/key, you will unnecessarily increase your burden for the preparation of the application, submission of Just-in-Time information, and annual reporting requirements.

Must we submit other support for all senior/key personnel?

Yes, submit the active other support for all senior/key personnel, regardless whether they are named in the NoA. This does not apply to OSC's. Nor does it apply to everyone listed in the All Personnel Report.

https://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm#1673
RPPR – Other Support

**Must we include all senior/key personnel in our response to SNAP question 1 (Has there been a change in the other support of senior/key personnel since the last reporting period?)?**

Yes, you must address the *changes* in other support for any individual you designated as senior/key personnel regardless whether they are named in the NoA. You must also include other support for any new personnel you designate as senior/key personnel. This question does not apply to OSC's. Nor does it apply to everyone listed in the All Personnel Report.

**Where do we address changes in level of effort for senior/key personnel not named on the NoA for SNAP awards? (i.e., senior/key personnel who are not addressed in SNAP question 2).**

In the SNAP progress report, you are not required to address changes in level of effort for senior/key personnel not named in the NoA. If you choose to address this, the appropriate place to do so is in the Progress Report Summary section.

https://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm#1673
Sponsor Related News
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
ORA provides review

The F-RPPR, in an ideal world...

**STEP 1:** Grant Manager (GM) engages with PI

**STEP 2:** PI works on and submits RPPR in eRA Commons!!!!!
NIH Implementation of Final Research Performance Progress Report (Final RPPR)

- No need to route to ORA for review and submission
- eRA Commons working on solution for delegation
DHHS (NIH) Operates Under a Continuing Resolution

When Congress and the president fail to agree on and pass one or more of the regular appropriations bills, a continuing resolution can be passed instead. A continuing resolution continues the pre-existing appropriations at the same levels as the previous fiscal year (or with minor modifications) for a set amount of time.

- NOT-OD-17-048
- Currently in effect until April 28, 2017
- NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level)
Continuing Resolution Continued

History of when Continuing Resolution was resolved:
• FY 2012 = December 23, 2011
• FY 2013 = March 25, 2013
• FY 2014 = January 17, 2014
• FY 2015 = December 16, 2014
• FY2016 = December 28, 2015
• FY2017 = TBD
• Source: https://www.senate.gov/legislative/appropsbills.htm
Continuing Resolution Continued

Awards issued under CR will continue to be processed as follows:

1. Project awarded in SPS Award at the reduced amount, however, full original budget sent to TBS
2. TBS will enter the amount held under CR in a restricted G/L in SAP
3. Once the restriction is lifted via a revised NOA, ORA will send only the revised NOA to TBS
4. TBS lifts the restriction in SAP
5. Department submits a rebudget to move the funding from the restricted G/L into the desired G/L

NOTE: This process will allow rebudgets completed prior to revised NOA to remain intact
Interim Guidance on Salary Limitation for Grants and Cooperative Agreements

• NOT-OD-17-049

• If adequate funds are available in active awards, and if the salary cap increase is consistent with the institutional base salary, grantees may rebudget to accommodate the current Executive Level II salary level

• No additional funds will be provided to grant awards

• Guidance from Duke:
  • Recommend the use of the new $187,000 salary cap for all new and non-competing applications submitted to DHHS and DHHS agencies (except FDA and Indian Health Services)
  • Applying the new salary cap retroactively to the effective date of January 8, 2017 is optional
NIH Grants Process Overview

https://grants.nih.gov/grants/grants_process.htm
NSF – Collaborators and Other Affiliations

- Effective April 24, 2017, the National Science Foundation will require the use of a specific NSF-developed spreadsheet for identifying collaborators and other affiliations
- Upload this information as a Single Copy Document that is seen only by NSF staff
- No longer include collaborator and other affiliation information in their biosketches
- The spreadsheet has been developed to be fillable; however, the content and format requirements must not be altered by the user
- Must be saved and uploaded as .xlsx or .xls only
- Will generate an error if not included in single and linked applications

https://www.nsf.gov/bfa/dias/policy/coa.jsp
PREVIEW: Revised ORA Grant Review Process

Improving consistency, accuracy, and collaboration while rewarding good administrative practices
The Current Process
The Approach

- Focus on the fundamentals
  - Improve accuracy
  - Improve consistency
- Simply identified what ORA reviews
  - Internal and external input
  - Weighted approach
- Develop systematic training and review process
  - Start with most important
  - Focus on fundamentals
- Communicate to community

- Abstract/SOW
- Budget - Cost Share
- Budget - F&A
- Budget - Other
- Budget - Students/Fellows
- Budget Justification
- Deadline
- DPAF- Completed
- Duke GAP
- Effort
- Export Controls
- IRB/IACUC
- Performance Sites
- Personnel - Roles, MOU, etc.
- Solicitation Specific Errors- FOA Specific Requirements
- Sponsor Standard Guidelines
- Subaward/Subcontracts
- Systems Validations
Level 1 Application Review:
- Abstract/SOW
- Budget - Cost Share
- Budget - F&A
- Budget - Other
- Budget - Students/Fellows
- Budget Justification
- Deadline
- DPAF - Completed
- Duke GAP
- Effort
- Export Controls
- IRB/IACUC
- Performance Sites
- Personnel - Roles, MOU, etc.
- Solicitation Specific Errors - FOA Specific Requirements
- Sponsor Standard Guidelines
- Subaward/Subcontracts
- Systems Validations

Level 2 Application Review:
- Budget - Cost Share
- Budget - F&A
- Budget Justification
- Deadline
- DPAF - Completed
- Effort
- Personnel - Roles, MOU, etc.
- Solicitation Specific Errors - FOA Specific Requirements
- Subaward/Subcontracts
- Systems Validations

Level 3 Application Review:
- Budget - F&A
- Deadline
- Solicitation Specific Errors - FOA Specific Requirements
- Systems Validations

Level 4 Application Review:
- Deadline
- Systems Validations

Draft
Reward Good Administrative Practices

- Reward complete, on-time applications
- Complete ‘Level 1’ review
  - Team review
  - Within 3 business days
- Goal: Submit 2 business day prior to deadline
  - Full NIH review window
ORA Team Review

- Only applies to on-time (Level 1) applications
- 2-4 Research Administrators
- Team completes only first review
- Complete review within 3 business days
- ORA rep still responsible for communication and follow up with departments
Level 1 Application Review:

> 7 Business days
- No waiver required
- Group review
- Goal to submit: 2 business days before deadline
- Full ORA review including:
  - Abstract/SOW
  - Budget - Cost Share
  - Budget - F&A
  - Budget - Other
  - Budget - Students/Fellows
  - Budget Justification
  - Deadline
  - DPAF - Completed
  - Duke GAP
  - Effort
  - Export Controls
  - IRB/IACUC
  - Performance Sites
  - Personnel - Roles, MOU, etc.
  - Solicitation Specific Errors
  - FOA Specific Requirements
  - Sponsor Standard Guidelines
  - Subaward/Subcontracts
  - Systems Validations

Level 2 Application Review:

7>4 Business days
- Application waiver required
- Goal to submit: 1 business day prior to deadline
- Limited ORA review:
  - Effort
  - Personnel - Roles, MOU, etc.
  - Solicitation Specific Errors
  - FOA Specific Requirements
  - Subaward/Subcontracts
  - Systems Validations

Level 3 Application Review:

4>2 Business days
- Application waiver required
- Submit by due date
- Limited ORA review:

Level 4 Application Review:

<2 Business days
- Application waiver required
- Submit by due date
- Limited ORA review:

To Be Continued...
Earliest Feb 5th Submission

- Earliest submission for R01 2/5 Deadline
- Date stamped from grants.duke
- Stedman Center
  - 1/30/17 @ 3:31 PM
  - Dr. Christopher Newgard
  - PAL: Shirley Austin
ORA Waiver

The Staff at Grants & Contracts advises you to
get your grant applications in EARLY!
Fewest Waivers

• FY17 Quarter 3
• Minimum 15 Submissions
• Tiebreaker to the department with the most submissions

DEPARTMENT OF PHARMACOLOGY & CANCER BIOLOGY

• 29 Applications
• No Waivers
ORA Shuffle

• Worked with the most ORA reps over the last year
• Exemplary patience and collaboration
A HUGE THANK YOU!!!

To each & every person who made a significant contribution to training by:

Reviewing new participant manuals, power point presentations, online calendaring tools, videos, checklists & other job aids

AND

Sharing spreadsheets, charts, stories of success, process overviews, suggestions, and best practices!
Do you have...

Practical suggestions, a model team, best practices or outstanding processes to share?

Or an interest in reviewing new training tools, materials or presentations?

If so, we welcome you!

Contact
Rachel.Monteverdi@duke.edu
Training

- NIH Application Development, Management & Resources – It’s Just In Time & the Notice of Award  
  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)  
  Wednesday, July 12

- eSubmissions –> Submitting applications electronically to sponsors  
  Wednesday, July 26
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<tr>
<td>NIH Application Development, Management &amp; Resources – The FOA – Part 1 of 2</td>
<td>Tuesday, October 31</td>
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<tr>
<td>NIH Application Development, Management &amp; Resources – The FOA – Part 2 of 2</td>
<td>Wednesday, November 8</td>
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<td>Sponsored Projects System (SPS): A Hands On Training</td>
<td>Wednesday, November 15</td>
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<td>NIH Application Development, Management &amp; Resources – Building Your Basic Budget Part 1 of 2</td>
<td>Wednesday, November 29</td>
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<tr>
<td>NIH Application Development, Management &amp; Resources – Building Your Basic Budget Part 2 of 2</td>
<td>Thursday, December 7</td>
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Upcoming Training Opportunities - Conferences

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

• NIH Seminar
  • New Orleans, LA; May 3-5

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

• NCURA National Meeting
  • Washington D.C.; August 6-9

• SRA International Annual Meeting
  • Vancouver, Canada; October 14-18
Pizza and Proposals

• May 18th 11:30 AM Erwin Square 837
• Open (well, kind of) hours to collaborate with ORA
• Conveniently timed before June 5th deadline
• Registration through LMS
• Space will be limited
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
LMS Credit Qtrly Mtg & Survey

- 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