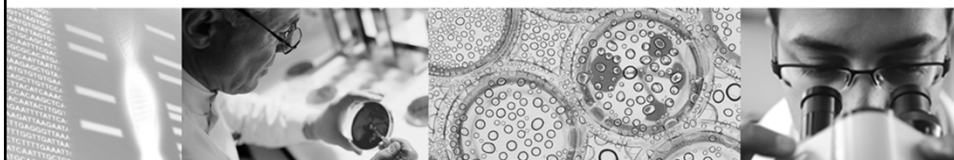


Quarterly Research Administrators Meeting

Office of Research Administration

April 21, 2016

 **Duke University**
School of Medicine



 **Duke University**
School of Medicine

Agenda

- **Research Administrator Portal (RAP)**
 - Laurianne Torres

- **RACI Closeout & Implementation Teams**
 - Team Updates

- **Office of Research Administration (ORA)**
 - Michael Dickman
 - » ORA News & Reminders
 - » Sponsor Related News and/or Tidbits
 - » Miscellaneous News and/or Tidbits




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Sponsor Related News and Tidbits

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eRA Commons Roles


➤ **eRA Commons accounts are set up with specific roles**
➤ **There are Administrative and Scientific roles.**


<u>Administrative</u>	<u>Scientific</u>
<ul style="list-style-type: none">• AA – Account Administrator• AO – Administrative Official• ASST – Assistant• BO – Business Official• SO – Signing Official	<ul style="list-style-type: none">• Graduate Student• IAR – Internet Assisted Review• PI - Principal Investigator• Post-Doc• Project Personnel• Scientist• Sponsor• Trainee• Undergraduate Student

https://era.nih.gov/files/eRA_Commons_Roles.pdf

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 Duke University School of Medicine	eRA Commons Roles
<ul style="list-style-type: none"> ➤ Each Department has a person(s) with the authority to set up and modify eRA Commons accounts ➤ Don't combine scientific roles with administrative or other roles on the same account <ul style="list-style-type: none"> • Other combinations are fine (e.g., PI and IAR; AO and FSR) • A person needing both scientific and administrative roles should have two separate accounts (one for scientific roles and another for other roles) ➤ The FOA may specify required eRA Commons roles for participants in an application ➤ Incorrect roles will cause grant applications to receive errors <ul style="list-style-type: none"> • Pay careful attention to subaward senior/key personnel! 	


 Duke University School of Medicine	K-Award
<h3>Other Support</h3>	
<ul style="list-style-type: none"> ➤ Proposal Stage for Mentored K <ul style="list-style-type: none"> • Modified OS is required with proposal for mentors/co-mentors. • Selected items, relevant to the candidate's research • No effort or overlap (does not require ORA review) ➤ Just In Time <ul style="list-style-type: none"> • Complete OS for candidate, mentor(s), other Sr./Key Personnel ➤ Progress Report <ul style="list-style-type: none"> • Active OS for Candidate, mentor, co-mentor, other Sr./Key • Only if OS has changed since last submission ➤ SF424 Application Guide Section 7.4 (always follow FOA specific instructions, which may differ from these general instructions) 	


K Awards

Effort Reductions

- **K Award salary costs are restricted; allowance is determined by institute**
- **Case Study**
 - PI proposed effort at 12 calendar months
 - PI received promotion and raise after submission
 - After award, PI reduced effort 24.9% to 9 months
 - » Cover raise
 - » Planned carryover

REVISION#1:
EFFORT REDUCTION FOR MENTORED AWARDS:
 With the award of _____ as requested by the recipient, the Principal Investigator's effort on this career award is being reduced from 12 calendar months to 9 calendar months. The budget has been adjusted to reflect the change. As required by NIH policy NOT-OD-08-065, the Principal Investigator should continue to focus on the development of her/his research career, have continued access to her/his mentor, and have his/her total level of research effort maintained and protected at a minimum of 9 calendar months.


NOT-OD-16-066

Final Invention Statement and Certification

- **All awardee institutions must submit Final Invention Statement (Form HHS 568) at the conclusion of a grant or contract**
- **All subject inventions must be reported in iEdison**
 - iEdison (Interagency Edison) is an online tool to report government funded inventions to the federal agency who made the award
 - Failure to report on inventions using HHS 568 and iEdison may result in organization's loss of rights in the invention or other actions as appropriate.
 - 37 C.F.R. 401.14(f)(5) <http://grants.nih.gov/grants/bayh-dole.htm#401.14>

Forms D (NIH & AHRQ)

- **We are reminded that the start date for the mandatory use of FORMS-D is May 25, 2016**
 - Must use FORMS-D for due dates on or after May 25, 2016
 - Must use FORMS-C for due dates on or before May 24, 2016.
- **Grants.Duke will be ready for use of the new forms by late April**
- **Please work with your RA if you have questions regarding the use of the new forms.**

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NIH & AHRQ Grant Application Changes for Due Dates On or After May 25

- Rigor and transparency in research grant applications (including small business and complex research grant applications) - [NOT-OD-16-011](#) and [NOT-OD-16-012](#)
- Vertebrate animals (NIH only) - [NOT-OD-16-006](#)
- Inclusion Enrollment Report Form – new, consolidated
- Data Safety Monitoring Plans – required for clinical trials
- Research Training - [NOT-OD-16-007](#)
- PHS Awarding Component and Peer Review Requests - [NOT-OD-16-008](#)
- New Font Guidelines - [NOT-OD-16-009](#)
- Biosketch Clarifications - [NOT-OD-16-080](#)

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Clarifications and Consolidated Biosketch Instructions and Format Pages


- Indicate that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography.
- Allow publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections
- State that graphics, figures and tables are not allowed.
- Remove the requirement that the past 3 years of research support are listed in order of relevance.
- Option to add other names used to author research products in section A.
- Research products can include conference proceedings such as meeting abstracts, posters, or other presentations.
- Research products that are under development, such as manuscripts that have not yet been accepted for publication, can be mentioned in the narrative sections. However, they cannot be cited as one of their citations.

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ORA News and Reminders

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New Forms D – Grants.Duke

Selecting the correct form set in Grants.duke

- Click on the Opportunity tab
- Select the correct competition ID (Forms-C or Forms-D)


Opportunity
Attachments
Check
Release
Print Preview

Opportunities for PA-13-302
Multiple opportunities match the entered FOA #.

Grants.duke has automatically selected the checked opportunity based on the CFDA Number and Opening Date. If this opportunity is not the one you wish to use, please select the correct opportunity from the following list:

	CFDA Number	Competition ID	Opening Date	Closing Date	Title
✓		FORMS-C	08/07/2013	05/07/2016	Research Project Grant (Parent R01)
Select		FORMS-D	05/05/2016	09/07/2016	Research Project Grant (Parent R01)

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New Forms D – Grants.Duke

Additional Attachments to PHS 398 Research Plan

- Data Safety Monitoring Plan in Human Subjects
- Authentication of Key Biological and/or Chemical Resources in Other Research Plan

Human Subjects

Protection of Human Subjects	Humans.pdf	View Attach Detach
Data Safety Monitoring Plan	Data Safety Monitoring Plan.pdf	View Attach Detach
Inclusion of Women and Minorities	Women.pdf	View Attach Detach
Inclusion of Children	Children.pdf	View Attach Detach
Enrollment Information		Edit/View

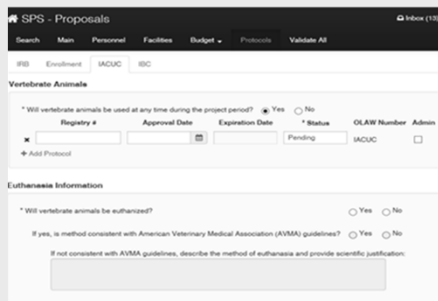
Other Research Plan

Vertebrate Animals	Animals.pdf	View Attach Detach
Select Agent Research	Select Agents.pdf	View Attach Detach
Consortium/Contractual Arrangements	Consortium_Arrangements.pdf	View Attach Detach
Resource Sharing Plans	Resource_Sharing.pdf	View Attach Detach
Authentication of Key Biological/Chemical Resources	Auth of Biological & Chemical Resources.pdf	View Attach Detach

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Additional Questions about Vertebrate Animals

- Are vertebrate animals euthanized? Yes/No
- If Yes, is method consistent with AVMA guidelines? Yes/No (conditional on 'Animals Euthanized' field)
- If No to AVMA guidelines, describe method/provide scientific justification (conditional on 'Consistent with AVMA' guidelines field)
- In SPS Web, a new section will be added to the IACUC tab to house the new fields.



The screenshot shows the 'SPS - Proposals' interface with the 'IACUC' tab selected. It features a table for 'Vertebrate Animals' with columns for Registry #, Approval Date, Expiration Date, Status, OLAW Number, and Admin. Below this is the 'Euthanasia Information' section, which includes radio buttons for 'Will vertebrate animals be euthanized?' and 'If yes, is method consistent with American Veterinary Medical Association (AVMA) guidelines?'. A text area is provided for describing the method and providing scientific justification if not consistent with AVMA guidelines.

Career Development (K-Award)

- **Added attachment for Candidate Information and Goals for Career Development**
 - Combines “Candidate’s Background”, “Career Goals and Objectives”, and “Candidate’s Plan for Career Development/Training Activities during Award Period” into a single document

Alert: NIH does not accept PDF attachment of Actual/Planned Enrollment information. Click here to go to SPS Web to edit/view Enrollment information. Alternatively, L

Introduction (if applicable)


Introduction to Application View Attach

Candidate Information

Candidate Information and Goals for Career Development	Candidate.pdf	View	Attach	Detach
Plan to Provide Mentoring	MentoringPlan.pdf	View	Attach	Detach

Other Career Development Award Attachments

Plans and Statements of Mentor and Co-Mentor(s)	StatementsofSupport.pdf	View	Attach	Detach
Letters of Support from Collaborators, Contributors and Consultants	Letters.pdf	View	Attach	Detach
Description of Institutional Environment	InstitEnviron.pdf	View	Attach	Detach
Institutional Commitment to Candidate (requires signature of chief/chair)	InstitCommit.pdf	View	Attach	Detach




New Forms D - Grants.Duke

Combining the Planned Enrollment Report and Inclusion Enrollment Report

Additions to the report:

- Delayed onset study? Yes/No
- Enrollment Type? Planned/Cumulative (Actual)
- Using an Existing Dataset or Resource? Yes/No
- Participants Location? Domestic/Foreign – Note: Field already exists in Planned Enrollment table; does not exist in Cumulative Enrollment table
- Clinical Trial? Yes/No – Note: Field already exists in the Proposal record
- NIH-Defined Phase III Clinical Trial? Yes/No – Note: Field already exists in the Proposal record

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New Forms D - Grants.Duke


- Clicking on “Enrollment Information – Edit/View icon” in Grants.Duke
- Link sends you to SPS to complete table
 - The alert box that included the link to SPS Web to edit enrollment data is being removed

Attachments

Alert: This box has been removed. If you are viewing Actual/Planned Enrollment information, click here to go to SPS Web to edit enrollment information. Alternatively, use the Edit/View link shown below in the table.

Introduction (if applicable)		View Attach
Introduction to Application		
Research Plan		View Attach
Abstract	Abstract.pdf	View
Project Narrative		
Bibliography		
Specific Aims		
Research Strategy		
Progress Report Publication List		
Human Subjects		View Attach
Protection of Human Subjects		
Data Safety Monitoring Plan		
Inclusion of Women and Minorities		
Inclusion of Children		
Enrollment Information		Edit/View

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New Forms D - Grants.Duke

PHS Assignment Requests


- **NIH is adding a new template as a part of Forms D which will be used to capture the following information:**
 - Funding component assignment preference
 - Study section preference
 - Individuals who should not review your application due to conflicts
 - Scientific areas of expertise need to review your application

Note: This information was previously included in the Cover Letter which was attached to SF424 R&R Cover Page template.

Other Attachments (if applicable)

PHS Assignment Requests (optional)	Edit/View
Cover Letter	View Attach
Item 12 - Other Attachment 1	View Attach

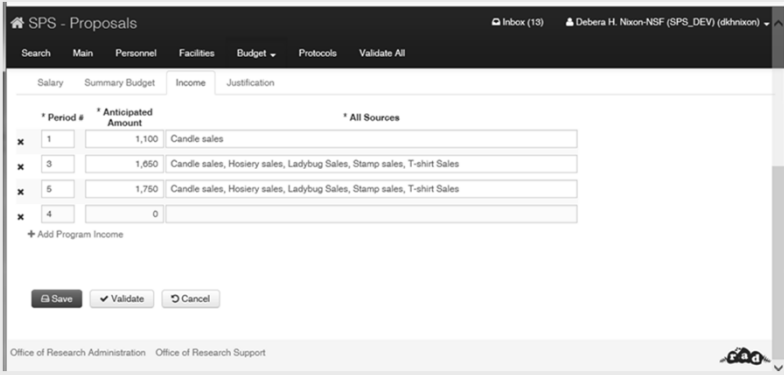
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New Forms D - SPS

Budget notebook – Program Income

- **Up to 10 budget periods of Program Income allowed**
 - Previously 5
- **'Add Program Income' link used to add up to 10 rows**



Office of Research Administration | Office of Research Support

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R&R Subaward Adobe Budget packet


- **Must be downloaded directly from the FOA**
- **Only edit in Adobe Reader**
- **Do not 'print' to a pdf file**
- **Check subrecipient for effort listed for all Sr/Key persons**
- **Justification must be pdf format (not MS Word)**
- **All years of the Project Period must be included, even if the subawardee isn't participating in one or more years**
- **Review packet for accuracy including:**
 - **DUNS number is correct subawardee**
 - **Budget amounts**
 - **Budget periods (adding years copies first year budget period)**
 - **Should not be modular**

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Online Web Form

- **Web Form Functionality**
 - No inbox
 - Cannot be marked urgent
 - Does not forward if someone is OOO
- **Appropriate contact (Grants, Federal Contracts, industry, DOCR)**
- **No longer used for NCE**
- **Do not use for contracts**
 - Use contracts management email for agreements (email)

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 **Duke University**
School of Medicine **Administrative Action Request**


Reminder: submit only one Administrative Action Request (AAR) form for each type of action

Examples:

- **Multiple WBSE Requests (when using more than one WBSE Request form) on one project – use 1 AAR form to submit the first 3, and send the additional forms via email to the RA.**
- **If selected ORA contact is OOO, forward AAR confirmation email to backup support. Do not need to resubmit new AAR and select new ORA contact**

Please do not submit an AAR to follow up on an AAR

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 **Duke University**
School of Medicine **NCE Tool**

- **Duke Approved vs. Sponsor Approved**
 - Depends on who has the authority to extend the project
 - Example: Foundation sponsor has sent PI an email extending project one year based on conversation at a conference. Dept. attaches confirmation email to NCE request and indicates as Duke or Sponsor approved?
- **Central Office vs Department Submitting Request to the Sponsor**
 - ORA defaults to department to submit NCE request to Sponsor
 - If ORA submitting request, department must include contact information in NCE memo field
 - When ORA approves NCE, auto-generated email will indicate who ORA expects to submit the request

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Rebudgets are created/initiated by the department. If initiated rebudget is no longer needed, only the initiator can delete the rebudget.

Question:

What happens if the initiator leaves their position in the department or leaves Duke all together?

Solution:

The Business Manager may place a ticket to the OIT Help desk to have the rebudget deleted. ORA cannot delete the rebudget.

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**FDP Subrecipient Commitment Form
pilot project participation**

- **40 institutions participating in pilot**
- **Reduce administrative burden between institutions**
- **Those participating must use FDP website to obtain sub's institutional information in lieu of multi-page form**
- **ORA will push back on pilot institutions that are asking for forms**
- **Information and participants are located at:
http://sites.nationalacademies.org/PGA/fdp/PGA_171520**

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F&A Overrides in SPS Web

➤ Subrecipient F&A

- Provide the name(s) for any sub-recipient that has already reached the \$25,000 threshold in a prior year
- Denote what portion of the sub-recipient's \$25,000 base is subject to F&A in the current year
- Each sub-recipient's F&A assessment is "separately" determined based upon each new scope of work
- Demonstrate how you computed the F&A by providing notes in budget memo, including a spreadsheet if needed


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F&A Overrides in SPS Web

➤ For Cases Where The F&A Rate is Less Than Full Recovery

- Please consult the School of Medicine's F&A Rate and Guidelines to determine if a waiver is needed
<https://finance.duke.edu/research/monitoring/farates.php>
- Use The Total Direct Costs [TDC] Based Instead of The Modified Total Direct Cost [MTDC] Base
- Note: Even if the mathematical computation in the proposal process is the same, due to re-budgeting on the post award side the F&A Base selected is important!

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ORA Proposal Tips

Other Electronic Submission Systems

- **Sponsors that have their own submission systems that do not connect to grants.duke**
 - Department is responsible for assuring and attesting that both systems agree
 - » Key personnel
 - » Total direct costs and total F&A
 - Attach the sponsor financial summary documents in the internal documents section of SPS Web
 - If a proposal is routed to ORA without sufficient time to resolve variances between systems prior to the submission deadline, ORA will file the proposal at the department's risk

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ORA Proposal Tips

Collaborate Early

- **Working with outside organizations**
 - SF424 packages for sub-recipients
 - » Department acts as liaison with sub-site during pre-award
 - » Department is responsible for accuracy of subaward package
 - Letters of intent/support for consultants
 - Quotes for vendors
 - Special applications
 - » Multi-institution applications

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Collaborate Early

➤ **Working with ORA**

- Not just 7 business days
- Keep your ORA point of contact informed regarding your application submission plans
- Hours of operation are 8 am to 5 pm M-F
- Staff work schedules vary – 7 am to 6 pm M-F
- ORA role is to act as the liaison between the department and the PI and/or their designee and not as the substitute for the departmental representative
- ORA will not make changes to last minute applications

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Collaborate Early

➤ **Working with Sponsors**

- Prior approvals
 - » Limited submission
 - » Requesting more than \$500K
- Use the Check feature in grants.duke throughout the proposal process as you upload attachments to identify any unexpected error messages
- Allow adequate time to resolve validation issues
 - » NIH allows 2 business days up to deadline
 - » After 2 business days, application must be formally withdrawn
- If there are problems with the transmission the department may need to file a help ticket with the eRA Commons help desk

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Miscellaneous News and/or Tidbits

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Professional Development Opportunities

➤ **Duke Education & Training Opportunities can be found and registered at:**

- <http://finance.duke.edu/research/training/index.php>
- Mandatory for RCC certifications: FY16 Management of Selected Post Award Issues (MSPA) classes have been scheduled



➤ **Professional Conferences:**

- NCURA Region III – Miramar, FL; April 29 - May 4, 2016
- NIH Regional – Baltimore, MD; May 11-13, 2016
- NCURA Annual – Washington DC; August 7-10, 2016
- SRA Annual Meeting – San Antonio, TX; October 22-26, 2016

➤ **Next Research Administration Quarterly Meeting**

- July 2016

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ORA Personnel Update

➤ **Arrivals**

- Teresa Chicarelli, Staff Specialist
- Ping Niou, Research Administrator – Contracting
- Virginia Wallace, Research Administrator – Contracting

➤ **Departures**

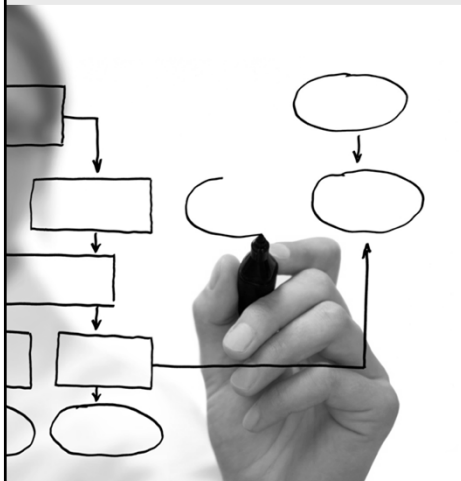
- George Curnow
- Katherine Scott

➤ **Openings**

- Research Administrator – Grants
- Research Administration Manager – Contracts

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LMS Registration & Credit




Patience with the Process, Please

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 (\$100 fee N/A)

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LMS Credit & Survey

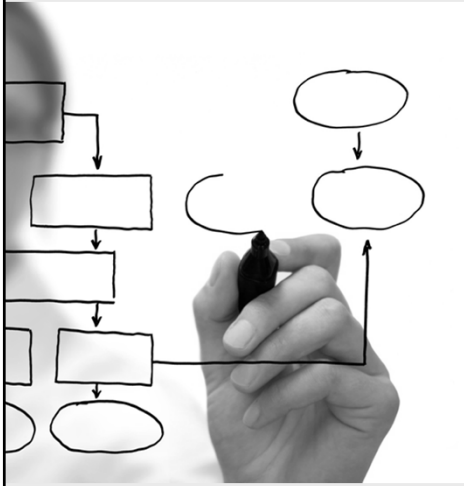
Patience with the Process, Please

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



Anonymize Response. Do NOT record any personal information and remove panel association (not recommended).

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Questions?

Please state your name and department

 **Duke University School of Medicine**

