Quarterly Research Administrator’s Meeting
Office of Research Administration
4/18/2019

AGENDA

Lindsey Spangler – Foreign Involvement in Research
Blake Perrault – myRESEARCHhome
Darrell Queen – WBSE Setup
Michael Dickman – ORA Update

International Collaborations
Duke’s Commitment to International Collaborations

- Duke University values our international collaborations in research and education and the scholars and students from around the world who contribute to our academic mission
- The University is committed to building and supporting an inclusive and diverse research community
- Such collaborations are vital to our work in advancing education, research, and health locally, nationally, and globally

“Statement on Protecting the Integrity of U.S. Biomedical Research”

Dr. Francis Collins, Director of NIH, laid out the following issues in an August 2018 statement:
- Failure by some researchers to disclose substantial resources from other organizations, including foreign governments
- Diversion of intellectual property in grant applications or produced by NIH-supported research to other entities, including other countries
- Sharing of confidential information in grant applications by NIH peer reviewers with others, including foreign entities

http://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research

It’s Not Just NIH…

- DoD - FY ’19 National Defense Authorization Act (NDAA) contains a number of provisions of relevance to science and security issues...
  - Sec. 885 requires DoD to develop procedures to limit foreign access to technologies through grants, contracts...
  - A report with assessments and recommendations for penalties for violations “including intellectual property forfeiture” is due Sept. 1 of next year.
  - DoD is working with a number of institutions to better understand individuals directly or indirectly interacting with DoD funded awards
- NSF:
  - Four institutions are currently subject to OIG inquiries that relate to work with talent programs and whether there is information that should have been reported in current and pending support, biosketches, and collaborations and affiliations.
- Department of Energy:
  - Review underway of all DOE Lab Employees that may also have talent program funding; anticipate expansion to universities.
NIH Research Projects Referred to OIG for Failure to Disclose Foreign Affiliations (February 06, 2019)

- WASHINGTON – In response to an inquiry from Senate Finance Committee Chairman Chuck Grassley (R-Iowa), the Inspector General for the Department of Health and Human Services indicated that the National Institutes of Health has recently referred for investigation a dozen allegations of noncompliance related to medical research. The inspector general noted that these referrals primarily dealt with the failure of principal researchers to disclose foreign affiliations.

- In addition, the inspector general noted that it has recently initiated evaluations to assess NIH’s vetting and oversight process related to research integrity and has initiated audits relating to NIH’s award process, including its process for assessing the potential risk of grant recipients.

NIH Focus
Adequate Disclosure to Manage
- Intellectual Property
- Peer Review Process
- Overlap (Scientific, Financial, Commitment)

Ongoing NIH Efforts
- Seek to mitigate and prevent (more than criminalize)
- Work with institutions and organizations
  - Dr. Collins letter to recipient organizations (August 21, 2018)
  - Communications to specific institutions: employment actions
  - Multiple interactions with members of Congress
- Work with partners across the government (including FBI)
- Peer review
  - Invitation to serve at agency discretion
  - Reporting to institutions and OIG
  - Enhance security
Ongoing Duke Efforts

• Training & Resources
• IT Solutions
• Communication
• Operations
• Education

Training & Resources

• Information will be posted on Grant Support website when complete
• Duke is continuing to monitor the issue and guidance received from NIH and other federal sponsors
• We expect NIH to issue additional guidance soon

Training & Resources

• Foreign component definition
  – where/when to indicate in initial submission
  – prior approval if added during the course of work
    • NIH GPS 8.1.2.10: Foreign Component Added to a Grant to a Domestic or Foreign Organization - Adding a foreign component under a grant to a domestic or foreign organization requires NIH prior approval
• Foreign Justification (required attachment)
Foreign Component Definition

• The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended

• Activities that would meet this definition include, but are not limited to
  (1) the involvement of human subjects or animals
  (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities
  (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country

Foreign Component Definition

• Examples of other grant-related activities that may be significant are:
  – collaborations with investigators at a foreign site anticipated to result in co-authorship;
  – use of facilities or instrumentation at a foreign site; or
  – receipt of financial support or resources from a foreign entity

Foreign Component and Justification

SF424 Form (New and Competing)

• If you have checked “Yes” to Question 6, you must include a “Foreign Justification” attachment in Field 12, Other Attachments
  – Describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting
  – In the body of the text, begin the section with a heading indicating “Foreign Justification” and name the file "Foreign Justification"

*We are working with the DRI RAD group to update SPS to better reflect requirements for a foreign component
Foreign Component and Justification

RPPR (non-competing)

Description of foreign component is limited to 700 characters

Requesting Prior Approval (SOM)

- Utilize the ORA Administrative Action Request form and select “Prior Approval Request”
- Attach foreign justification file describing special resources or characteristics of the research project, including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting

Training & Resources

- Biosketch and Other Support
  - Include collaborative grants, awards, and relationships/positions outside of Duke and the US, even if no salary support
- Grant acknowledgment in publications & progress reports
  - Co-authored publications involving foreign collaborators/institutions
Publications
Using PMC ID from progress report, review collaborating authors and grant support on PubMed Central

Review author information at top of page for foreign co-authors

Review acknowledgments near bottom of page for foreign grant support

Conflict of Interest

• Accurately disclose foreign financial interests and relationships in your Duke Annual COI Disclosure Form in accordance with Duke policies and federal regulations
• Further information on COI disclosures is available through the Duke Office of Scientific Integrity and the Office of Research Support. Examples of a foreign financial interest include, but are not limited to the following:
  • Payment for service from a foreign government, company, or academic institution such as a consulting fee, lecture payment, or honorarium
  • A gift from a foreign government, company, or academic institution such as money, hospitality, or a physical item
  • An equity interest in a foreign company such as stock, stock options, securities, or other ownership interest
  • An intellectual property right such as a patent, copyright, or royalty from such right

Foreign Travel

• Investigators with research sponsored by the U.S. Public Health Service (PHS) are required to disclose certain information about all sponsored or reimbursed travel that meets certain criteria:
  - Travel that is reimbursed or sponsored by an external entity
  - Travel is related to institutional responsibilities to Duke (e.g., speaking about your science, as opposed to an unrelated topic, like a hobby)
• Foreign entity sponsored/reimbursed travel is treated differently than domestic—no exemption
• Exemption only applies to domestic institutions of higher education (as defined in 20 U.S.C. § 1001(a)), a federal, state or local government agency, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education
Foreign Travel

• Use Duke’s Sponsored Travel form to report travel (https://radapps.duke.edu/phs_travel)
• Provide:
  – The identity of the sponsor/organizer (if the sponsor is a company but they are working through a marketing company, report the primary sponsor of the trip rather than the intermediary);
  – The purpose of the trip (speaking, consulting, meetings, etc.);
  – The destination for the trip; and
  – The duration of the travel, specifically the date you left and the date you returned

Export Controls

Consult the Office of Export Controls website before:
• traveling abroad on academic business
• collaborating with international partners, either formally or informally
• making international financial transactions
• shipping materials internationally
• transferring technology
• using restricted materials for research

Duke - Communication

• Communication to all faculty engaged in research sent February 14, 2019
• Communication to SOM grant administrators sent February 22, 2019
Duke - Education

- Research Town Hall – May 6, 2019 (see next slide)
- Research Administrators Symposium – May 29th
- Individual School/Department meetings – to be scheduled (e-mail Geeta.Swamy@duke.edu)
- ORA/ORS Quarterly Meetings
- Business Manager Meetings
- RCC Mandatory Grant Manager and Business Training

Duke - Research Town Hall
(May 6, 2019)

International Collaborations at Duke

1) Researcher Perspectives
   - Panelists will include investigators with foreign collaborations
2) Grant Compliance
   - Overview of foreign component definition, requirements for foreign justification, biosketch, other support, and grant acknowledgment in publications

Duke - International Research Collaborations
Upcoming Meetings

<table>
<thead>
<tr>
<th>Faculty/Leadership</th>
<th>Research Administrators</th>
<th>Business Managers</th>
<th>Research Community</th>
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</thead>
<tbody>
<tr>
<td>RRAC (3/8)</td>
<td>RA small group (2/28)</td>
<td>Campus AFLG (3/12)</td>
<td>Research Town Hall (5/4)</td>
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<tr>
<td>Clinical Chairs (TRB)</td>
<td>CRU FPM (3/13)</td>
<td>SOM Business Managers (4/4)</td>
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<tr>
<td>Basic Chairs (TRB)</td>
<td>ORS CRAM (4/1)</td>
<td>Mandatory Training (Spring/Summer)</td>
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<td>Deans Cabinet (3/2)</td>
<td>ORA Quarterly (April 18)</td>
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<tr>
<td>Center/Institute Directors (4/6)</td>
<td>MSPAI (May-June)</td>
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Departments/Center/Institutes
- Surgery (2/23)
- Pathology (3/12)
- Ophthalmology (3/13)
- BM (3/22)
- Dermatology (4/16)
- Immunology (4/3)
- MGH (4/12)
- CFM (4/25)
What you need to remember:
- Integration of SPS and SAP
- Department/Center/Institute initiates for WBSEs in advance of award and new Sub codes for existing WBSEs
  - Includes awards with annual renewals (DHHS sponsored)
- Central offices initiate for WBSE at Award in Progress/Award
  - Department reviews prior to creation in SAP
- Resources: Quick Reference Guide and Online Video Tutorials available on the Finance Website

Additional Offering Available!
When: Wednesday April 24 (9-10:30 A.M.)
Where: Erwin Square 8th floor Conference – RM 837
How to Register: Search “WBSE Create Overview Session” or follow the link below
https://lms.duhs.duke.edu/Saba/Web/Cloud/goto/OfferingDetails?offeringId=class000000095997

If you have yet to attend a session, we encourage you to sign up or to send a representative.
Comments

• Add notes if different central approver is needed on the WBSE (similar to Proposal Memo)
  – Industry – Cory Puryear
  – Federal Contracts – Rob/Marianne/Wendell

Routing

• Central offices add additional central office approvers
• Departments add additional department approvers

Cancel

• WBSE ‘In-Progress’
  – Deleted in SPS
  – Anyone with edit access to the record may delete
Cancel WBSE

- Routed to SAP Workflow
  - Delete in workflow
  - Only the Initiator can delete

Other Tips

Issues inputting names
  - Hit enter or click the box

WBSE request gets locked
  - Close browsers, clear cache
  - Let us know if you hit 24 hours

ORA NEWS AND REMINDERS
ORA Personnel Update

- Arrivals
  - N/A
- Departures
  - N/A
- Openings
  - Training Coordinator

John Michnowicz
Assoc Dean / Exec Dir
Shannon Geddes
Research Admin (RA)
Susan Chase
Staff Assistant
Michael Dickman
Assoc Dir
Gabriel Smith
Research Admin (RA)
Teresa Chicarelli
Research Admin (RA)
Chantal Whitfield
Research Admin (RA)
Patricia Davis
Research Admin (RA)
Carol Smith
Res. Admin Mgr (RAM)
Christina Jackson
Research Admin Mgr (RAM)
Mariah Codoley
Research Admin (RA)
Barbara C. Hall
Research Admin Mgr (RAM)
Amy Barbee
Research Admin Mgr (RAM)
Brooks Fuqua
Research Admin (RA)
Erinn Nichols
Research Admin (RA)
Cynthia Wicker
Staff Specialist
Dana Hewitt
Research Admin Mgr (RAM)

Pre-award, Award Mgmt
DCRI Specialist
Edu & Training
Assoc Dir
Pre-award and Award Mgmt
Special projects
Pre-award Admin, Sp Prj
Martin Friedman
Research Admin (RA)
Catherine Sciambi
Research Admin Mgr (RAM)
Broderick Grady
Assoc Dir – International Vacant
Training Coordinator
Administrative Support
IPAs, PSAs, MOUs & Grant Portfolio
Adam King
Research Admin Mgr (RAM)

VA MOU
SOM Research Administration community is to use the “updated” MOU (June 2018) version when submitting a new or updated MOU.

Changes include:
- Specific “Effective Date” of MOU is requested
- VA signature delegated to Faculty member’s Immediate VA Superior
- Duke signature approval delegated to Div. Adm. or Div. Chief
- Information will still be reviewed, verified and stored by ORA

https://medschool.duke.edu/research/research-support-offices/office-research-administration/veterans-affairs-mous

Invite us to your staff meetings

Collaborate!

VA MOU
VA MOU

SOM Research Administration community is to use the “updated” MOU (June 2018) version when submitting a new or updated MOU.

Reminders:
• Though ORA signature was removed, ORA (Barbara Hall) still reviews and approves
• VA MOU required at NIH application submission
  NIH GPS Part II Subpart B Section 17.3
  – If signed MOU is not available, please note in proposal memo and send efforts to obtain signature to ORA (e.g. email to VA)
  – ORA may help facilitate signatures or grant exemption to submit app

https://medschool.duke.edu/research/research-support-offices/office-research-administration/va-partnering-office-research-administration

NIH Budget Justification
VA vs TPE Statement
• VA Statement
  – Must be included if PI has VA appointment
  – Example: The effort requested represents the share of Duke University time only; Dr. Andy Biotic has a 3/8 VA appointment.
• Total Professional Effort (TPE) Statement
  – Must be included if PI has <50% Duke appointment
  – Statement to clearly represent actual calendar months dedicated to the project
  – Should include in non-NIH budget justifications
  – Example: Dr. Andy Biotic 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.

iForm 180 Day Calculator

https://medschool.duke.edu/research/research-support-offices/office-research-administration/award-management/special-projects

Is the proposed iForm effort change greater than 180 days?
Copy Functions

- State restrictions have been lifted for the following Copy functions:
  - Copy as Non-competing Renewal
  - Copy as Competing Renewal
  - Copy as Supplement
  - Does not apply to composite

- Ability to insert final year Non-competing Renewals in between the previous Non-competing Renewal and a Competing Renewal

Performance Sites

- Duke performance sites
  - Combined % Used = 100%
  - ORA address auto-populates and is preferred, may be changed to PI/department address
  - Documents appropriate application of F&A

- Non-Duke performance sites
  - % Used = 0%
  - On/Off-Campus is dependent on sub location (not Duke's)
NIH Filename Validations

- Filenames used for grant application attachments must be:
  - descriptive;
  - unique within an application (or within a component of a multi-project application);
  - comprised of the following characters: A-Z, a-z, 0-9, underscore, hyphen, space, period, parenthesis, curly braces, square brackets, tilde, exclamation point, comma, semicolon, apostrophe, at sign, number sign, dollar sign, percent sign, plus sign, and equal sign; and
  - 50 characters or less (including spaces).

https://grants.nih.gov/grants/ElectronicReceipt/esub_items_interest_02282019.htm

eRA systems now enforce the long-standing 50-character limit for filenames used for attachments in grant applications. The file name length will be checked by ASSIST and other solutions that use our validation service pre-submission, so remember to keep those file names short!
Examples of non-compliance we found:

- Under Education & Training - no baccalaureate listed
- Personal Statement (Section A) - four publications may be cited, this bio sketch has five
- Contributions to Science (Section C) - five contributions are allowed with up to four publications cited. This bio sketch has too many citations in 2 of the 5 contributions
- The Research Support (Section D) - list support from the past 3 years that the PI wants to draw attention to. The entries are supposed to list goals of the projects and the individual’s responsibilities. This bio sketch doesn’t have either
- This bio sketch also includes “Section E – Additional Information.” This section is not part of the format or instructions.
- Utilizes an old template
Compliant Other Support

Updated other support for all key personnel (including subcontracts). NIH is critiquing very closely the other support which is submitted. PLS. NOTE:

• We cannot emphasize enough that this request is only for KEY persons. The persons stated with effort on the top half of the budget pages for the first year of this fund.
• Total effort cannot exceed 12 cm including effort on this ‘to be funded project’.
• Grant numbers for NIH projects need to be stated.
• Do not state projects which have expired.
• If ‘pending’ projects have now been awarded, please state within the ‘Active’ section of the document.

GrantSupport.Duke.edu

Important NIH Info

In response to recent changes in requirements from the NIH, several new efforts to enhance proposal development, submission, financial oversight, and research integrity have been introduced to further strengthen Duke’s research infrastructure and administration. As a reminder, the following is now required for all Duke NIH awards:

- Detailed Budgets - for all modular applications (not just RFAs) and RFPs effective April 1, 2018
- Carryover requests - prior NIH approval for all effective May 15, 2018
- No cost extensions requests - prior NIH approval for all effective April 1, 2016

This website provides information and guidance necessary for faculty and grant managers across Duke to comply with NIH’s requirements. We will continue to keep you updated vis this website as we learn more from NIH. See Updates for latest information.

Please let us know if you have questions or concerns - email grantsupport@duke.edu.

GrantSupport.Duke.edu

Updates

04/03/2019 NCI Request Process - templates and other resources have been updated
04/04/2019 Town Hall Series - Upcoming Event May 6, 2019
02/16/2019 Town Hall Series - Upcoming Event April 10, 2019
02/16/2019 NCI Training Grants - page added
01/15/2019 NCI Training Grants - page added

Tools and Resources - page updated to include NCI Training Grants letter
Other Professional Training Opportunities

• NCURA Region III
  – Hollywood Beach, FL; May 5-8
• NIH Seminar
  – Baltimore, MD; May 15-17
• NCURA Annual Meeting
  – Washington D.C., Aug 4-7
• SRA Annual Meeting
  – San Francisco, CA; Oct 19-23
Pizza and Proposals

- May 20, 2019, Noon
- Erwin Square 837
- Open hours to collaborate with ORA
- Registration through LMS
- Watch for emails

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