Quarterly Research Administrator’s Meeting
Office of Research Administration
7/19/2018

AGENDA

Jim Luther – NIH Update
Blake Perrault – myRESEARCHhome
Michael Dickman – ORA Update
FOR EARLY ACCESS, QUESTIONS or FEEDBACK

blake.perrault@duke.edu

my R E S E A R C H home

mrh.duke.edu

ORA NEWS AND REMINDERS
ORA Personnel Update

• Arrivals
  • Mariah Codoley
  • Gabriel Smith
  • Jae Furman
  • Cindy Wicker

• Departures
  • Taylor Filippini

• Openings
  • None

Collaborate!

Invite us to your staff meetings
NEW FELLOWS!

Daniel Jordan
Lynn Ta
Rimel Mwamba
Spencer Lamb

Security Officers

- Each department should have an SPS security officer set up
- Responsibilities include:
  - Managing access to SPS on behalf of the department
  - Manage BFR routing (path and contacts)
- Requires SPS Legacy
  - Phasing out
  - Accessed through desktop app or Citrix
- Who is your SPS security officer?
  - Reach out to your senior department grant manager
- ORA does not manage these assignments
Updated VA MOU

Effective immediately, the 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/va-partnerships/veterans-affairs-mous

SPECIAL CONSIDERATIONS FOR DOD SUBMISSIONS
DOD Application Tips

- The business official (set up during LOI or pre-application time) must be Michael Dickman (gcmail@mc.duke.edu) for ORA to be able to see application
- Partnering applications must follow instructions sent via email from eBrap/initiating application
- Proposal Log Number should be entered into Agency ID field in SPS

DOD Funding Level Options

The FY17 OPORP OPORA offers funding for two Funding Levels. The following are generalized descriptions of the scope of research appropriate for each Funding Level:

- **Funding Level 1/New Investigator**: This level is for new investigators only, and may support pilot research without preliminary data or research that is already supported by preliminary data and has the potential to make significant advancements toward clinical translation. Specific eligibility details are provided in Section II.C. Eligibility Information.

- **Funding Level 2**: Research that is supported by preliminary data and has the potential to make significant advancements toward clinical translation.

Specific eligibility and funding information is provided in Section II.C. Eligibility Information and Section II.D.5, Funding Restrictions.

The anticipated total costs budgeted for the entire period of performance for an FY17 OPORP OPORA Funding Level 1/New Investigator will not exceed $500,000. The anticipated total costs budgeted for the entire period of performance for an FY17 OPORP OPORA Funding Level 2 will not exceed $2.5M. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

http://cdmrp.army.mil/funding/pa/FY17-OPORP-OPORA.pdf
DOD Proposal Memo

Proposal memo should include:
1. level of funding applicant is applying to, when appropriate (e.g. Level 2 funding option)
2. information whether or not it is a single application or partnering application (and who is initiating versus partnering), when appropriate

Example proposal note: PI is responding to Level 2 funding option and is a partnering PI (P1). Initial application is in Department of Medicine (SPS xxxxxx). Additional partner (P2) is at Mayo Clinic and their budget is $xxx,xxx.

DOD Budget

• All partnering application budgets roll into overall budget limit
• DOD does not have a salary cap, do NOT follow the NIH salary cap
• Fringe benefit rates must be Duke’s current negotiated DHHS agreement rate for all years
# Grants.Duke Attachments

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# DOD Attachments

- Documents need to be named per guidelines in application submission checklist
  - Special instructions for abstract:
    - The grants.duke attachment must be named SOW.pdf
    - The abstract name in SPS should be abstract.pdf
    - The two documents cannot have the same name

- OS is required at PCA and must be attached in ‘Personnel’ tab under ‘Other info’ in SPS
DOD Attachments Grants.Duke

• Additional Attachments section
  – Additional attachments become available as attachments are uploaded (up to 15 attachments)
  – Must be attached in submission checklist order
  – May be rearranged after upload

DOD Attachments Grants.Duke

• Partnering applications in Grants.Duke:
  – Not all attachments are required for the partnering application
  – Attachments must still be included in the correct order and place
  – Documents not required for the partnering applications must still be uploaded in Grants.Duke in the appropriate order
    • These documents must include statement that document is included in the initiating application
DOD Application Submission and Review

- PI releases application in Grants.Duke
- PI will be notified of submission via email
- Strongly encourage reviewing the application in eBRAP post-submission

SPECIAL CONSIDERATIONS FOR NIH COMPETING SUBMISSIONS

• The Cover Letter should be used for any narrative information you want to relay to NIH receipt and referral staff, such as:
  – Reason for late application
  – Explanation of why a Subaward isn’t active in all periods of the proposed project
  – Statements regarding agency approval documents (e.g., requests over $499,999)
  – Intent to submit a video as part of the application (NOT-OD-12-141)
  – Indication that the proposed study will generate large-scale human or non-human genomic data (NOT-OD-14-111 and NOT-OD-15-027)

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.200-sf-424-(r&r)-form.htm#21

• NIH added PHS assignment request form effective May 2016
  • Captures 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

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.600-phs-assignment-request-form.htm
PHS Assignment Requests

- Requests made in the PHS Assignment Request Form may be used to expedite the processing and assignment of applications
- NIH receipt and referral staff are only looking for assignment requests in the PHS Assignment Request Form
- NIH does not guarantee to honor requests, though they try to do so whenever possible
- Do NOT include assignment request in the Cover Letter

Admin Salary Indicator
Admin Salary Indicator

- Located on the Roster of Duke Personnel
- Indicates when a role on the project is administrative/clerical (CAS)
- Only use for personnel whose duties on the project are solely administrative
- Justification should support admin duties and integral role to the project
- Helps ensure budget is set up correctly at Duke (no CAS rebudget necessary for personnel)

Administrative Salary

GAP 200.360, Charging Clerical And/Or Administrative Expenses To Federally Funded Projects

- The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:
  - Administrative or clerical services are integral to a project or activity;
  - Individuals involved can be specifically identified with the project or activity;
  - Such costs have the prior written approval of the federal awarding agency; and
  - The costs are not also recovered as indirect costs.
Type 2 Application - TC Limits

- Some NIH Institutes have budget caps for Type 2 applications (competing renewals)
- Guidelines and enforcement vary by institute
- Recent issues with NCI and NIAID
  - NIAID https://www.niaid.nih.gov/grants-contracts/apply-renewal

If non-personnel CAS expenses are included in the application budget, I do not need to submit a CAS rebudget to be able to spend on the GL

- True
- False
SPECIAL CONSIDERATIONS FOR NIH RPPR

NOT-OD-18-202

Synchronization of Institutional Delegations for RPPRs

- NIH has modified the RPPR module within eRA Commons to automatically incorporate the same delegation options available to institutions within the annual RPPR
Decimals in Effort Reporting

• NIH has changed its RPPR format to allow effort reported in grant applications to include decimals
• Until now, the system only allowed whole numbers and rounded up or down accordingly, leading to inaccurate reporting

B.4 What opportunities for training and professional development has the project provided?

• For all projects reporting graduate students and/or postdoctoral participants in Section D., describe whether your institution has established Individual Development Plans (IDPs) for those participants. Do not include the actual IDP, instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.
• Duke does not have institutional IDPs
D. Participants

D.1 What individuals have worked on the project?
• In part D of the F-RPPR (participants), should we report time worked for the final budget period or time worked for the final budget period + the no cost extension period?
• In the Final RPPR you should report on the individuals that worked on the project during the last budget period minus any approved no-cost extensions. You can find this and more in the RPPR FAQs.

D.2 Personnel Updates

D.2.a Level of effort. Will there be, in the next budget period, either
• a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award?
• a reduction in level of effort below the minimum amount of effort required by the Notice of Award?
D.2 Personnel Updates

- 8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA
- Prior approval is required if PD/PI or other Senior/Key Personnel specifically named in the NoA
  - Withdraw from the project entirely
  - Will 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

D.2 Personnel Updates

- 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
  - Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more.
  - Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level.

Selecting **Yes** in the RPPR constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.
D.2 Personnel Updates Examples

Duke receives 20% cut in the initial award from NIH; therefore, the PI reduces effort 20% from 4 months to 3.2 months to match. For year 2, the PI wants to decrease effort from 3.2 months to 3 months.
D.2.a Will there be, in the next budget period, a reduction of 25% or more in the level of effort?

- PI committed 6 months effort to grant
  - 01 RPPR – PI reducing effort to 5.4 months
  - 02 RPPR – PI reducing effort to 4.8 months
  - 03 RPPR – PI reducing effort to 4.2 months
  - 04 RPPR – PI reducing effort to 3.6 months
  - 05 RPPR – PI reducing effort to 1.8 months

In which RPPR(s) should the PI have marked 'Yes' to effort reduction in the RPPR?

- 01 RPPR – PI reducing effort to 5.4 months
- 02 RPPR – PI reducing effort to 4.8 months
- 03 RPPR – PI reducing effort to 4.2 months
- 04 RPPR – PI reducing effort to 3.6 months
- 05 RPPR – PI reducing effort to 1.8 months
Once *agency approval* has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level.

**Does selecting 'Yes' in D.2 of the RPPR constitute a prior approval request to the agency?**

- Yes
- No
G.4 Human Subjects
G.7 Vertebrate Animals

8.1.2.5 Change in Scope
• Potential indicators of a change in scope include, but are not limited to, the following:
  – Substitution of one animal model for another.
  – Change from the approved use of live vertebrate animals.
  – Change from the approved involvement of human subjects that would result in an increased risk.
• Changing from ‘No’ to ‘Yes’ and vice versa typically requires NIH prior approval.

G.10 Estimated Unobligated Balance

FORM: G. Special Reporting Requirements
Questions: G.10 - G.12
G.10 Estimated Unobligated Balance

• G.10.a – Is the estimated unobligated balance greater than 25%?
  – Check with your OSP Liaison if you have questions verifying the amount

• G.10.b – Provide explanation for unobligated balance
  – Please provide justification for the balance

• G.10.c – IF authorized to carryover the balance, provide a general description of how it is anticipated the funds will be spent
  – “NIH has issued Duke University Specific Award Conditions (SACs) effective March 12, 2018 for which one of the SACs removed automatic carryover of unobligated balances. As a result, Duke University will formally submit a prior approval carryover request detailing how carryover funds will be used within the existing/current budget period once the Final Financial Report (FFR) is submitted.”
How should effort be reported for PI with .6 calendar months in the all personnel report?

- 0 calendar months
- 0.6 calendar months
- 1.0 calendar month

Don’t include because less than 1 calendar month.
Final Invention Statement (FIS)

• PI must initiate the FIS in eRA Commons
Final Invention Statement (FIS)

- In eRA Commons, PI must certify either:
  - No inventions were conceived, or
  - Add information on inventions conceived during the project
- Routes to SO (ORA department rep) in ORA

- ORA confirms PI certifications with OLV
- Submits to NIH in eRA Commons

NIH Fixed Price Prior Approval Clarification

- On June 5, NIH issued a clarification email to COGR/FDP on fixed price prior approvals
- Clarification allows us to classify clinical trial sites as “fixed rate” instead of “fixed price”. Fixed rate agreements will not be subject to prior approval requirements or the simplified acquisition threshold.
- This can only be used for clinical trial site/capitation agreements that pay per-patient or per-procedure where the total amount of the subaward may be unknown (e.g. how many patients will be enrolled)
- Other sponsors (DoD) have similar carve-outs, but you should consult your grant terms and conditions to make sure
- NIH NOT should be issued soon and a revision to the Grants Policy Statement is expected in the fall
Relinquishing Statement

- A Relinquishing Statement is a declaration by the original grantee institution that it has agreed to relinquish responsibility for an active grant. This must occur before the expiration of the approved project period.
- The relinquishing statement may be submitted email or electronically via the eRA Commons.
- A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement or the available balance in PMS, whichever is less.
- OSP will have a role in the relinquishment/project transfer process – OSP is reviewing for costing elements in determining the reasonableness of the remaining balance for transfer, as well as specific compliance matters.

NIH Relinquishing Statement and Project Transfers

- The Department will forward the completed Relinquishing Statement or specific transfer documentation, as is required by other sponsors, to OSP.
- Forward the Statement/all transfer documentation to OSP using this email address - sponsoredprograms@duke.edu - OSP will triage your correspondence and assign the documentation for review.
- If questions arise, the GM/Department will be contacted by an OSP Liaison for additional information.
- Upon completion of the review, OSP will advise (via email) both the GM and ORA, and will forward the Relinquishing Statement/transfer documentation to the pre-award office.
- ORA will perform any additional reviews and submit to the sponsor to begin the official process.
VA Effort on Duke Other Support

- Some departments have included VA projects on Duke OS
- Duke cannot verify effort on non-Duke projects
- NIH does not specify whether institutions should include VA support on OS, but encourages institutions to be consistent
- Moving forward do not include VA effort on OS

GrantSupport.Duke.edu

Duke University NIH Grant Administration Guidance

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 (at Just-in-Time) and RPRRs effective April 1
- **Carryover requests** - prior NIH approval for all effective May 15
- **No cost extension requests** - prior NIH approval for all for existing grants effective April 1

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 via this website as we learn more from NIH. See Updates for latest information.
Open Mike “It’s not MY Grant?”

https://nexus.od.nih.gov/all/2018/05/29/waitits-not-my-grant/

- The key to success in grants management is a close working relationship between institutional officials and investigators, and communication and coordination with NIH.
- NIH staff work with designated AORs for compliance matters related to the award.
- The designated PD/PIs closely partner with their institutional officials to ensure appropriate responsibility and accountability for the proper conduct of research.
- If an investigator has questions about their roles and responsibilities on an NIH grant, their first stop should be the sponsored programs office at their institution.

PROFESSIONAL DEVELOPMENT AND TRAINING UPDATE
Other Professional Training Opportunities

- NCURA National Meeting
  – Washington DC; August 5-8
- NIH Seminar
  – San Francisco, CA; October 17-19
- SRA International Annual Meeting
  – Orlando, FL; October 27-31

Pizza and Proposals

- Sept 17, 2018, Noon
- Erwin Square 837
- Open hours to collaborate with ORA
- Registration through LMS
- Watch for emails
2018 Dates - (Tentative)

Training

Sponsored Projects System (SPS): A Hands On Training – Please bring a laptop if possible
Erwin CR837
Thursday, August 2, 2018
8:30 am – 12:30 pm

Other Support, Primarily for NIH
Erwin CR837
Thursday, August 16, 2018
8:30 am – 12:00 pm

NIH Research Performance Progress Reports (RPPRs)
Erwin CR837
Tuesday, August 28, 2018
8:30 am – 12:15 pm

Sponsored Projects System (SPS): New Session: Thursday, September 13, 2018
8:30 am – 12:30 pm

Unofficial Information in Red; Official dates & times will be in LMS 30 days prior to class
Contact Rachel.Monteverdi@duke.edu with questions

2018 Dates - (Tentative)

Training

Intergovernmental Personnel Act (IPA) & the VA
Erwin CR837
Wednesday, Sept 26, 2018
8:30 am – 12:00 pm

Memorandums of Understanding (MOUs) & Personal Service Agreements (PSAs)
Erwin CR837
Wednesday, October 10, 2018
8:30 am – 12:00 pm

RA Quarterly Meeting
Bryan Research Building 311 Research Drive
Thursday, October 11, 2018
1:30 pm – 4:30 pm

NIH Application Development, Management & Resources – The FOA – Part 1 of 3
Erwin CR837
Wednesday, October 24, 2018
8:45 am – 11:45 am

NIH Application Development, Management & Resources – The FOA – Part 2 of 3
Erwin CR837
Wednesday, Oct. 31, 2018
8:45 am – 11:45 am
### 2018 Dates - (Tentative)

**NIH Application Development, Management & Resources – The FOA – Part 3 of 3**
- **Wednesday, Nov. 7, 2018**
  - 8:45 am – 11:45 am

**Sponsored Projects System (SPS):**
- A Hands On Training – Please bring a laptop if possible
  - **Tuesday, Nov. 13, 2018**
  - 8:30 am – 12:30 pm

**NIH Application Development, Management & Resources – Building Your Basic Budget**
- **Thursday, Nov. 29, 2018**
  - 8:45 am – 12:00 pm

**NIH Application Development, Management & Resources – Building Your Basic Budget**
- **Wednesday, Dec. 12, 2018**
  - 8:45 am – 12:00 pm

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**THANK YOU to those who have contributed to training!**

Reminder, if you have...
- Practical suggestions, best practices or outstanding processes to share
- OR
- If you have an interest in reviewing new training tools, materials or presentations

We need you!
- Contact Rachel.Monteverdi@duke.edu

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Unofficial Information in Red; Official dates & times will be in LMS
30 days prior to class
Contact Rachel.Monteverdi@duke.edu with questions
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 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