What we’ll cover...

- 5-part Communication Series
- Prior Review of Applications for External Funding
- Effort Management and Monitoring
- Common Errors in Proposal Development
5-part Communication Series
Background

• 5-part communication series beginning Jan 10 - as follow-up to help investigators navigate the recent updates to research policy

• Planned topics for 5-part communication series:
  1. Navigating the Proposal Review & Submission Process
  2. Understanding Roles, Responsibilities & Partnerships throughout the Pre-Award Stage
  3. Developing a Successful Budget
  4. Collaborating with External Partners / Subcontractors
  5. Knowing the Resources & Services Available to Support You

• Information will also be integrated into myRESEARChpath, training modules, and other resource platforms

• Ideas for content? Email Laurianne Torres – laurianne.torres@duke.edu
Prior Review of Applications for External Funding
Background

• Long-standing Duke requirement for all applications for external funding be review/cleared by the institution prior to submission
  • Recent communication in August 2021 research policy updates and January 2022 memo to research leaders
  • Duke has received several awards for proposal not routed for institutional approval in advance

• ORA responsible for ensuring adherence to federal laws, regulations, sponsor policies and institutional policies, which must be managed prior to submission

• Effective immediately, any research-related applications submitted to an external sponsor without first receiving institutional clearance from the appropriate pre-award office will not be accepted at the time of award notification
Prior review is required for any application for external funding that will be awarded to Duke University - examples include:

- Collaborating on a new project (or non-competing renewal) with another organization that will be the prime (Duke will be a sub) – including the Durham VA
- Collaborating with an industry partner as a pass-through entity (funds originate from another source, such as Federal)
- Providing quotes for Duke shared resources (including as a sole source provider)
- Proposing a pilot project (either direct from Duke or through another organization)
- Proposing to a sponsor that does not require an institutional signature (Duke still requires institutional review/approval)

Also, non-competing renewals and final progress reports (RPPRs) require prior review before submission
What does not require Prior Review...

Because the sponsor does not typically require a detailed budget, official commitment of Duke resources, or authorized institutional signature, prior institutional review is not required for:

- White papers
- Letters of Intent to apply
- Pre-Proposal

In these cases, prior ORA review is not required unless otherwise specified by the sponsor. The PI submits directly to the sponsor and no SPS record is required.

Please note: Though the prior review policy does not apply in this case, the business unit may have a requirement for review.
Prior Review and Internal Deadlines

- Duke policy requires proposals be received in final form (submission ready) by ORA at least five (5) business days in advance of the submission date
  - Calculating the five business day deadline

- If an error is discovered that would affect ORA’s ability to certify that the proposal contents are true, complete, and accurate, certain changes may be allowed (for example: tables or figures)

- In rare, extenuating circumstances, when the 5 business day deadline cannot be met, a late waiver may be requested (subject to institutional review approval)
  - Late waiver requests, and expedited or after-the-fact review
Prior Review and Internal Deadlines

• Please note Duke University (via an authorized organizational representative-AOR) is obligated by its sponsors to review and approve the final versions of all application documents prior to submission
  • Know who Duke’s authorized organizational representatives are

• Answers to frequently asked questions are in myRESEARCHpath (requires login)

• Coming soon! Revised timelines and requirements for non-federal applications
Key Takeaways

Understand advance review requirements

• The process and system for submitting a proposal depends on the sponsor and type of application
• Your grant manager can guide you

Use Intent to Submit

• Use the “Intent to submit” process in myRESEARCHhome at least 15 business days in advance of the intended submission date

Meet the 5 business day internal deadline

• Submission-ready proposals must be received in ORA at least five (5) business days in advance of the submission date
• How to calculate the five business day deadline

More information and answers to frequently asked questions are in myRESEARCHpath: Review and submit the proposal | myResearchPath (duke.edu)
Effort Management and Monitoring
Background

• Federal agencies’ increased scrutiny of Other Support and Person Months available for research

• Greater scrutiny by the Office of Research Administration (ORA) throughout project lifecycle (from proposal to close-out)

• RACI project to review existing policy/process, implement new systems, along with communication/training updates

• Effort monitoring - area of focus for Duke Office of Audit Risk and Compliance (OARC)
Sponsor Expectations

• Effort and salaries of investigators and other project staff charged to sponsored projects are assigned in a manner that is:
  • Fair
  • Consistent
  • Accurate
  • Timely

• Effort allocated is a *reasonable estimate of actual effort expended*

• Effort commitments are *reasonable* and are *met* (or *adjusted*, with prior approval if necessary) to complete goals/aims of the project
## What are the risk areas?

<table>
<thead>
<tr>
<th>Reducing Effort</th>
<th>Disclosing PI Disengagement</th>
<th>Adhering to committed or required effort levels</th>
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</thead>
<tbody>
<tr>
<td>• ≥25% without sponsor approval of Key Personnel</td>
<td>• Leaves of Absence, Sabbatical, Flexible Work Arrangements</td>
<td>• Not charging effort</td>
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<tr>
<td>• Exactly 24.9% to avoid sponsor approval</td>
<td>• Outside Appointments (e.g., Duke-NUS)</td>
<td>• Not taking TPE into consideration to ensure adequate person months are protected</td>
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<tr>
<th>Addressing overcommitments</th>
<th>Ensuring all projects have PI committed effort</th>
<th>Allocating effort appropriately</th>
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<tr>
<td>• Greater than 90-95% externally-funded</td>
<td>• Key named on NOA w/ no effort</td>
<td>• Not allocating effort once project work commences</td>
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<td>• Full time Duke appt w/ significant outside activities (e.g., ≥ 5/8ths VA appt)</td>
<td>• Aggregated effort of 0% on OS</td>
<td>• Shifting effort near end of project to spend down available budget</td>
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Duke Expectations

1. When adjusting effort of key personnel during the course of the project, seek prior approval in advance¹

   • Any change (addition or removal) in a key person specified in the application or the Federal award; or

   • A 25% or greater reduction of time devoted to the project by the approved project director (PD) or principal investigator (PI) or other named Key Personnel; or

   • Reducing the investigator’s Duke TPE thereby decreasing the total available time at Duke to conduct research; or

   • Disengagement from the project for more than three (3) months
     • includes leaves of absence, sabbatical, flexible work arrangements, or any outside appointment that reduces the investigator’s total available time at Duke to conduct research

¹If required by award terms & conditions or as outlined in Uniform Guidance § 200.308
2. Fulfill minimum / required effort commitments

• Certain awards have terms and conditions that require the investigator to maintain a minimum effort level (for example, NIH Research Career Development “K” awards and NCI Minimum Level of Effort)

• It may be necessary to adjust Total Professional Effort (TPE) distribution to ensure effort requirements are calculated against a Duke full-time appointment and there is appropriate protected Duke effort for the sponsored project(s).
3. If an investigator takes leave, information is received timely

- Inform unit-level leadership (Chair/Director) *in advance* and secure appropriate institutional approvals

- Coordinate all sponsor communication (*including prior approval*) with the Office of Research Administration (ORA)
Unacceptable Practices

- **Reducing effort just below the threshold** (for example, 24.9%) to avoid seeking sponsor prior approval

- **Rotating charges among sponsored projects without establishing actual benefit** to each sponsored project or activity

- **Allocating effort based only on available sponsored funds**, budgets, or to avoid restrictions imposed by law, terms of the sponsored award, or for other reasons of convenience

- **Charging effort exclusively to sponsored projects** when effort supports non-sponsored activities

- **Assigning effort to sponsored projects or activities in advance of the benefit** to the project
## Key Takeaways

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<tr>
<th>Ensure <em>timely</em> allocation</th>
<th>Review effort <em>regularly</em></th>
<th>Review all effort</th>
<th>Keep effort <em>current</em></th>
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<tr>
<td>• Establish a pre-award code to where applicable / appropriate</td>
<td>• Monthly meeting with grant manager</td>
<td>• Confirm reasonable estimate of actual effort of all activities, not just sponsored activity</td>
<td>• Communicate with grants manager any planned changes in work schedule and/or TPE and if effort allocation is not correct</td>
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<td>• Have a plan for potential gaps in effort</td>
<td>• Remember to consider new and/or missing effort allocations</td>
<td>• Obtain prior approval for significant changes in key personnel effort</td>
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<td>• Use Duke@Work reports</td>
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Common Errors in Proposal Development
In response to requests for a “review checklist” from ORA, myRESEARCHpath content created to support smooth proposal submission.

Common Errors and How to Avoid Them provides tips and resources in several categories:

- General
- SPS Record Creation
- Budget
- Budget Justification
- Biosketch
- Resources / Facilities
- Human / Animal Subjects
- Cover Letters / Letters of Support

This is a living document – information will be updated regularly so please bookmark this page and visit it often!

Ideas for content? Email Laurianne Torres – laurianne.torres@duke.edu
Errors Preventing Submission

The best way to ensure a smooth submission is to complete the required Intent to Submit at least fifteen (15) business days in advance of the submission date so that grant managers can plan / help you navigate the steps to submission as early as possible and avoid these errors that could prevent submission of your proposal:

• Final documents not received
• The internal deadline not met
• Proposal attestation not completed
• Proposed Principal Investigator not eligible to serve as PI
• An irreconcilable issue from the required changes list
• Application (with approved waiver) is received with less than two days for review
Helpful Content in myRESEARCHpath

Click to visit

Common Errors and How to Avoid Them in myRESEARCHpath
Questions?

ORA’S GOAL IS TO PROVIDE effective, efficient, compliant and responsive support TO ADVANCE DUKE’S RESEARCH

PLEASE EMAIL ME IF YOU HAVE CONCERNS OR QUESTIONS!

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