Office of Research Administration

Quarterly Research Administrators Meeting

1/26/2017

Agenda

RCC Update – Jim Luther & Julie Cole

Clinical Trials – Jessica Houlihan

GCP – Lorna Dula

International Update – Broderick Grady

ORA Update - Michael Dickman

RCC Update

ORA Quarterly Meeting

January 26, 2017

Julie Cole, Director

Research Costing Compliance

Topics

- QuickStart Program Update
- AGM Update
- Reminder: Continuing Education Credits
- Reminder: Evaluations
- RCC Alert and the Grants Management Community News

QUICKSTART PROGRAM

WHAT IT IS

A "quick start" in introductory knowledge and basic skill sets in Research Administration at Duke

Introduction to Research Administration at Duke	Introduction to Compliance at Duke	Introduction to Pre-Award Administration at Duke (I &II)	Introduction to Post-Award Administration at Duke (I & II)	"Capstone" Forum

Six on-demand, self-paced online training modules with companion references and step-by-step guides, with a "Capstone" hands-on class for basic skills assistance.

HOW IT WORKS

Open enrollment curriculum for self-enrollment through the Learning Management System (LMS)

- ✓ No application process for QuickStart
- ✓ Designed to be easily navigated to allow participants to be able to move at his or her own pace and to gain access to all information and materials even after the training modules have been completed
- ✓ A supervisor's guide is included to support onboarding training

BENEFITS

Supports onboarding of new employees with research administration responsibilities

- ✓ Provides baseline, core knowledge for any and all employees responsible for managing sponsored research projects
- ✓ Provides introductory knowledge and skills to be able to contribute to departmental grant management within the first 90 days of hire

SKILLS

With departmental support and guidance, participants will be familiar with the following skills at completion:

- ✓ Navigate the Duke GAPs
- ✓ Navigate the SPS system to support proposal development
- ✓ Process a No Cost Extension request
- ✓ Process a Cost Transfer using the CT Tool
- ✓ Read and understand Master Data
- ✓ Process cost distributions via the Grants Management tab
- ✓ Assist with processing Closeouts

QUICKSTART GUIDE

This guide is designed to support supervisors during the initial 90 days of new research administrators . It is intended as recommended guidance only, and the actual assignment of duties is dependent upon department needs.

Key Elements & Skills Provided in QuickStart

- ✓ Understand the basic functions of research administration and how it is managed at Duke University
- ✓ Understand the basic compliance rules for research administration
- ✓ Perform limited, basic functions:
  - ✓ Perform a No Cost Extension
  - ✓ Perform a Cost Transfer using the CT Tool
  - ✓ Review/Adjust Master Data
  - ✓ Process cost distributions via the Grants Management tab
  - ✓ Assist with processing Closeouts
- ✓ Note: The SPS class offered by ORA is open enrollment if basic skill in SPS entry is desired as a supplement to QuickStart

Recommended System Access for New Grant Managers

- SPS (Sponsored Program System)
- SAP (r3 – Financial System)
- Grant Manager Tab
- Refer to the System Access Tool for further detail

Recommended Other Training in first 90 days

- Introduction to Duke Accounting and Business Practices
- Introduction to Duke General Ledger Accounts
- SPS (Sponsored Program System – SOM class, Campus ORS provides

Recommended 90 day assignments with initial department supervision

- Cost transfer (with supervision)
- No Cost Extension Request Basic cost distribution changes
- Closeout checklist

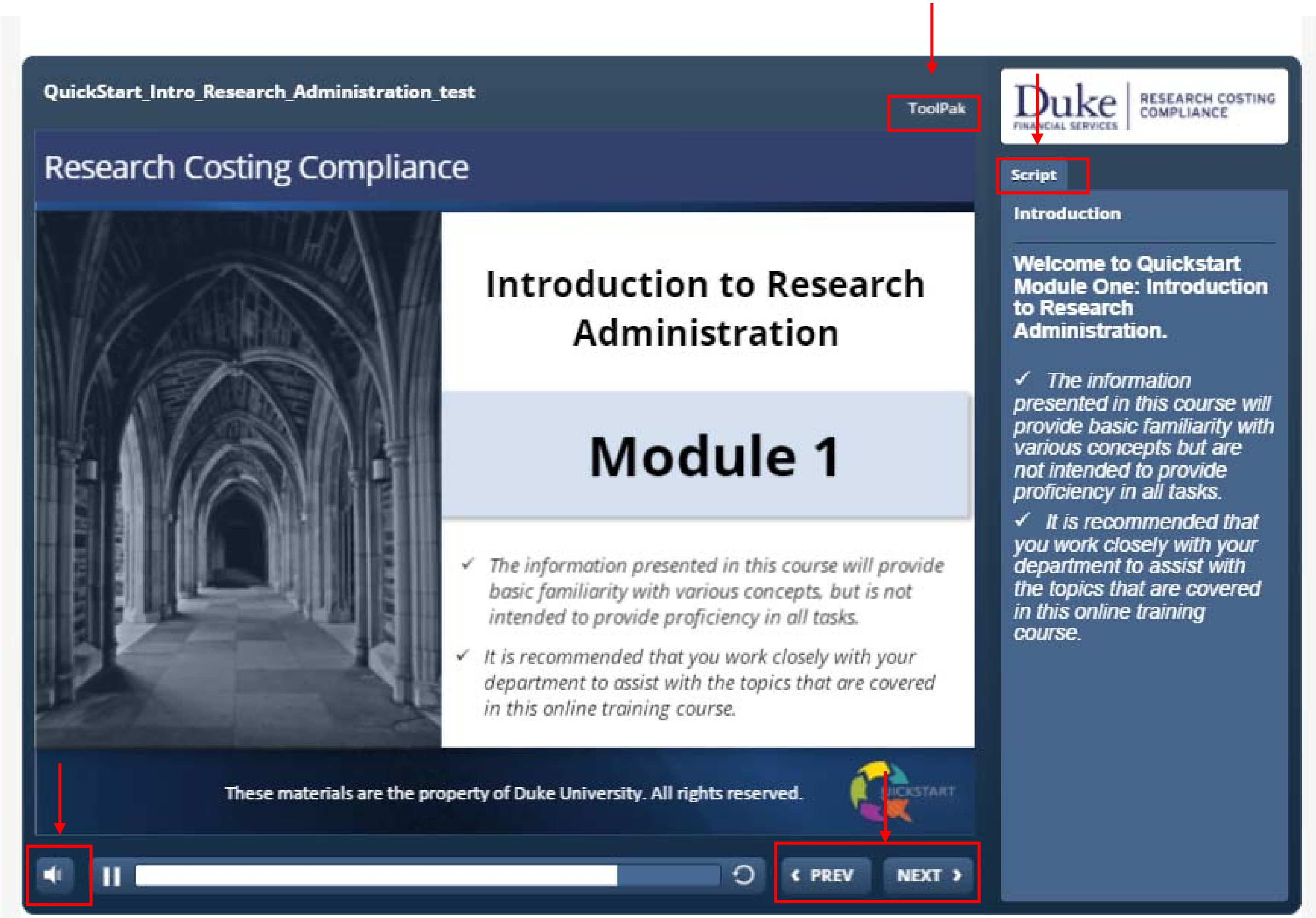
ToolPak Guide

- Basic post-award functions
- NOA and award setup basics
- Duke post-award systems and offices
- Basic SAP reports and GM tab
- Post-award financial function overview
- Basics of closeout and tasklist function

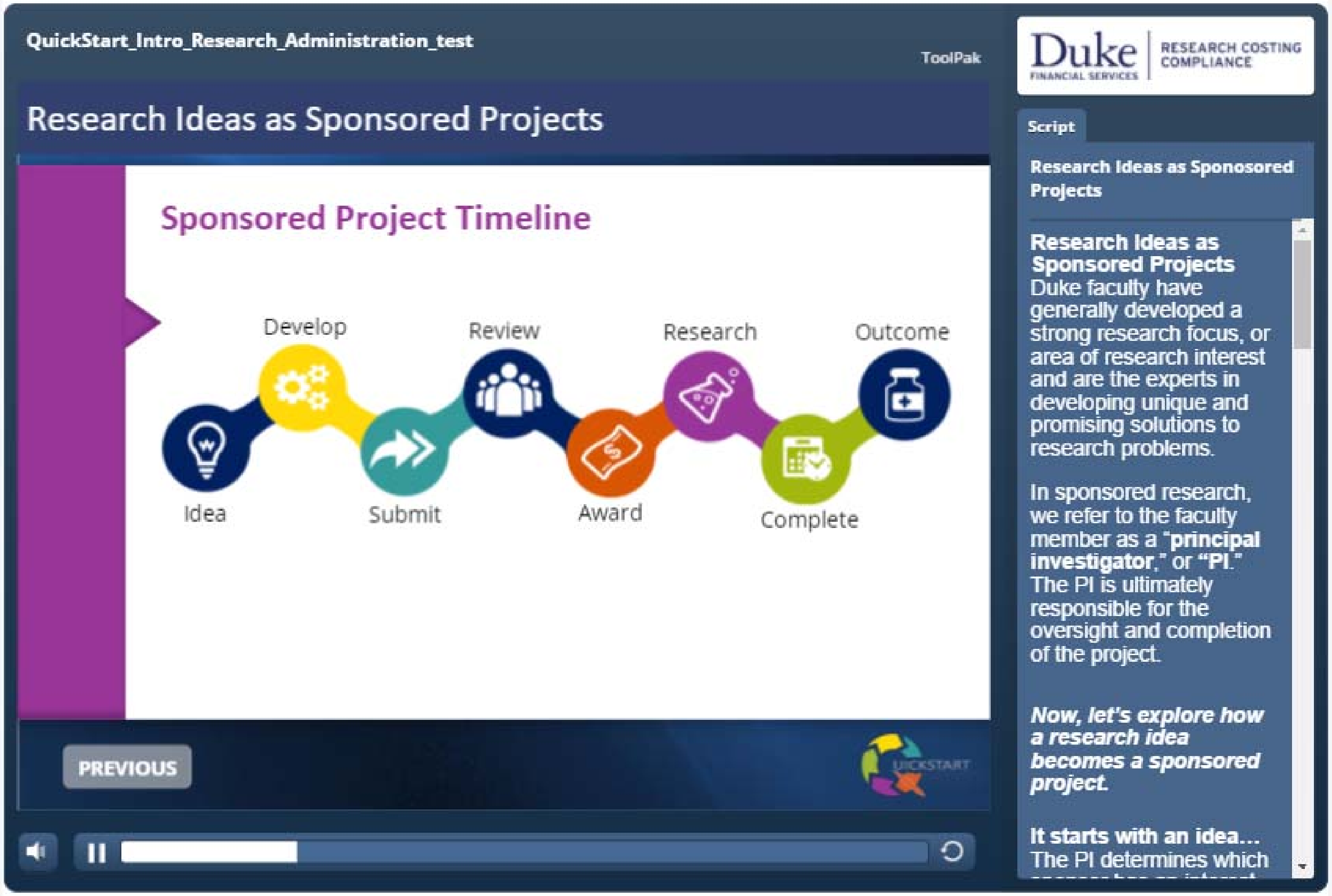
"Capstone" Forum

- Enroll in "Capstone" class as soon as modules are completed
- Supervisors should guide employees as to relevant questions, additional information needed, and recommended "hands-on" training desired during the capstone experience

SAMPLE: Key Features: ToolPak, narration, navigation and script for easy reading.

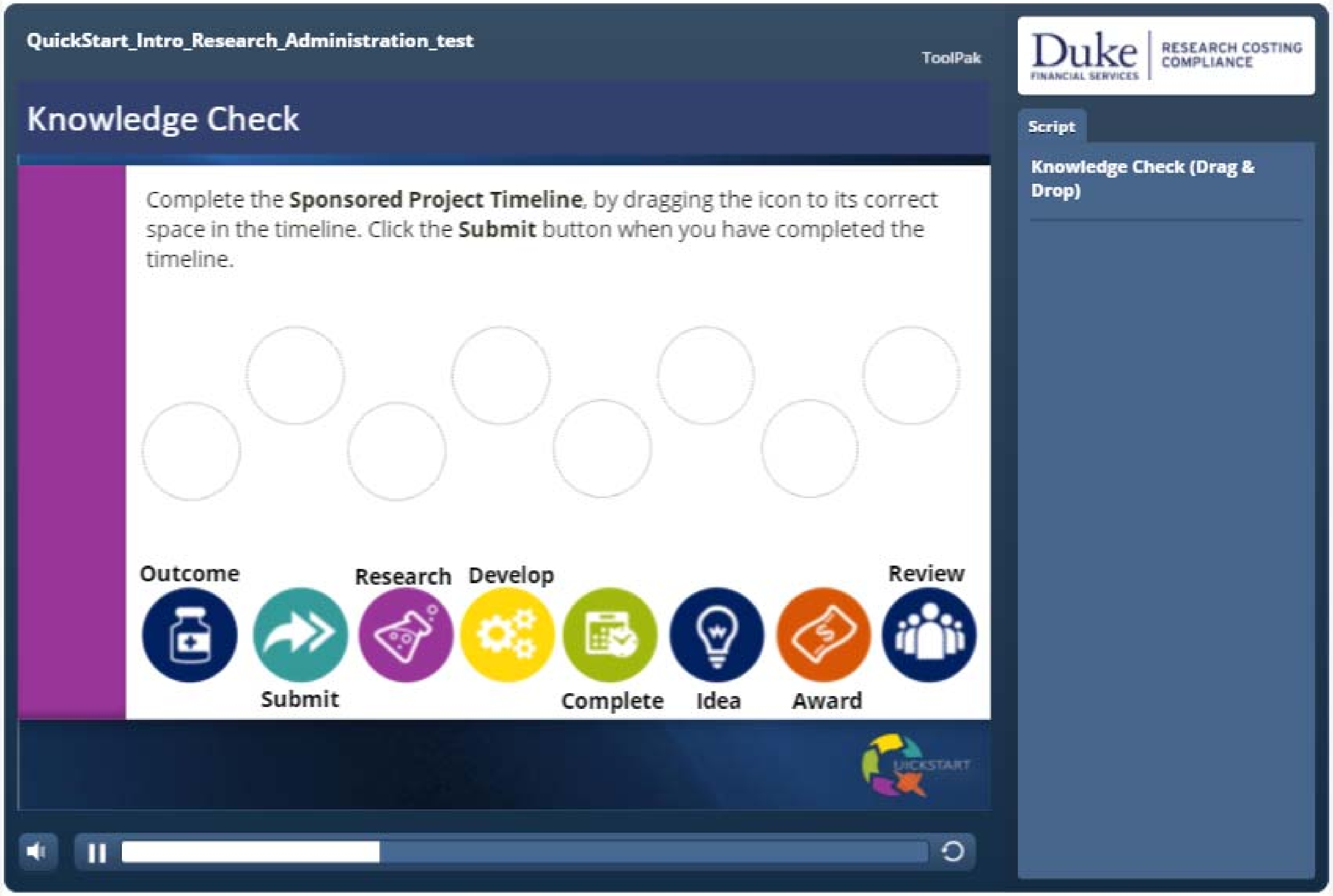


SAMPLE: Animated graphics with narrative



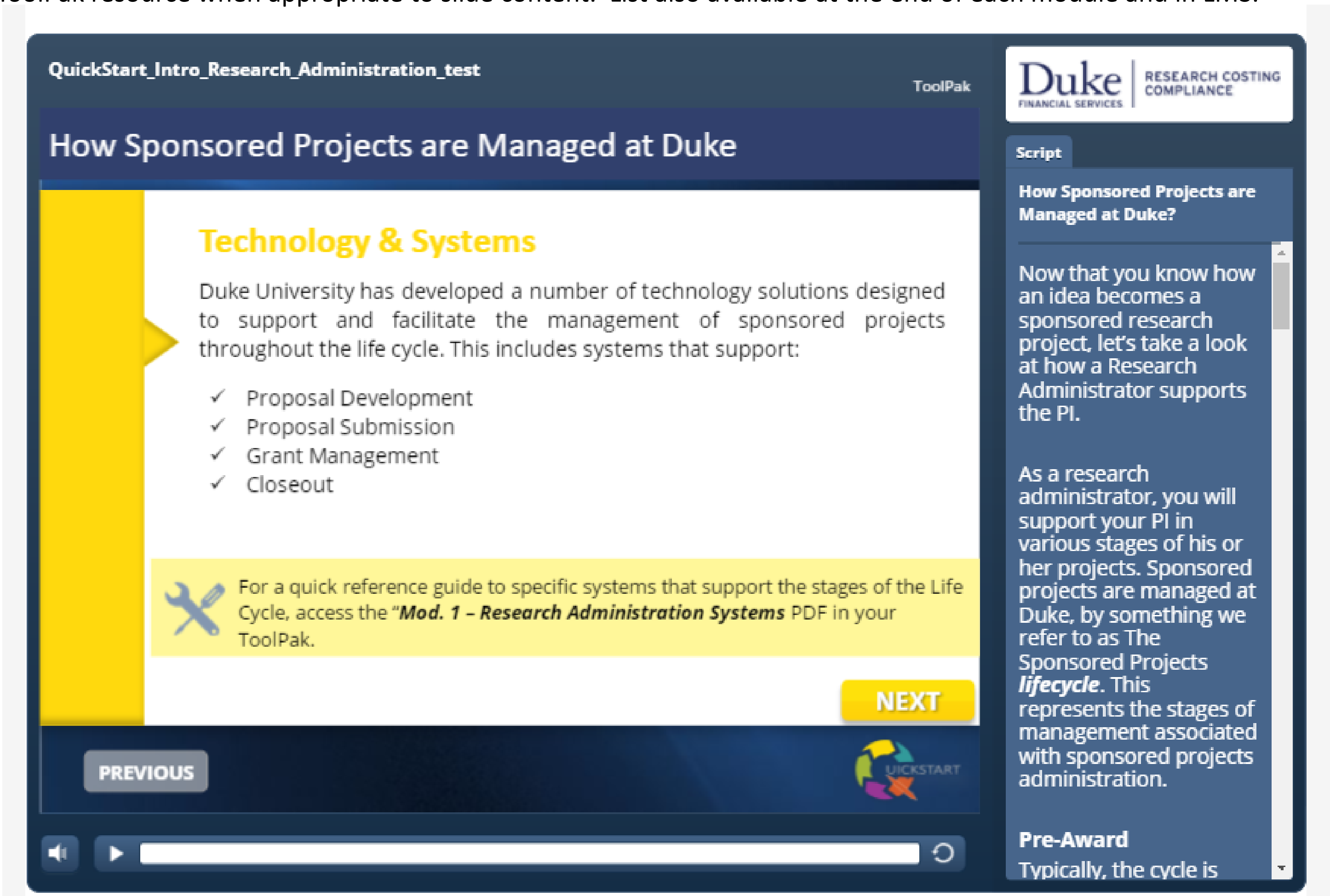
SAMPLE: Knowledge Check

Interactive Activities during the modules to test for understanding.



SAMPLE: ToolPak

Reference materials (ToolPak) are imbedded within the module for easy download. Banners remind participants to refer to a ToolPak resource when appropriate to slide content. List also available at the end of each module and in LMS.



SAMPLE ToolPak ITEM

Research Administration Systems PDF

RESEARCH ADMINISTRATION SYSTEMS AT DUKE UNIVERSITY

- ✓ SAP (also known as R/3)
- ✓ Grants Management Tab
- ✓ Universal Worklist
- ✓ Effort Certification Reporting Technology (**ECRT**)
- ✓ Buy@Duke

- ✓ Sponsored Projects System (SPS)
- ✓ Grants.duke

- ✓ Sponsored Projects System (SPS)
- ✓ Sponsored Effort System (SES)
- ✓ SAP (also known as R3)

LIFE CYCLE STAGE	SYSTEM	WHERE TO FIND
PROPOSAL & BUDGET DEVELOPMENT	**Sponsored Projects System (SPS)** Supports Duke University with proposal and budget development. Budget development is supported by automatic calculation of fringe benefits, indirect costs, inflation adjustments and modular grant offsets for NIG proposals.	To gain access to SPS, contact your Pre-Award Office. For Campus, contact ORS For SOM & SON, contact ORA
PROPOSAL & BUDGET SUBMISSION	**Sponsored Projects System (SPS)** The proposal routing system used by Duke University for tracking departmental and central office review and approval of grant submissions.	
	Grants.duke A website that ties the SPS to the federal Grants.Gov system, allowing a system-to-system submission of NIH, DOE and many DOD proposals.	https://grants.duke.edu/
AWARD & PROJECT SET UP	**SAP** Application used for University and Health System core administrative processes, including accounting, human resources, payroll, purchasing financials, ordering materials and paying employees. SAP is used at award set up to verify "master data" via CJ03 transaction and verifying awarded budget entry into the system by using the ZFR1E transaction.	To gain access to SAP, contact your system administrator within your department/unit. For more information, visit: http://finance.duke.edu/systems/sap/signup.php
	Sponsored Effort System (SES) Allows central grant offices to update awarded effort information and allows departmental users to view active and pending effort for personnel supported on grant funds. SES is used at the Award & Project Set Up stage to review effort commitments for personnel supported on sponsored projects. For updates needed in the system for SOM.SON employees, contact your pre-award office.	To gain access to SES, contact your Pre-Award Office. For Campus, contact ORS For SOM & SON, contact ORA

LIFE CYCLE STAGE	SYSTEM	WHERE TO FIND
AWARD & PROJECT MANAGEMENT	**SAP** Application used for University & Healthy System core administrative processes, including accounting, human resources, payroll, purchasing financials, ordering materials and paying employees. SAP is used during the life of Award Management to review expenses and verify activity using various SAP transactions.	To gain access to SAP, contact your system administrator within your department/unit. For more information, visit: http://finance.duke.edu/systems/sap/signup.php
	Duke@Work Online Portal A website that supports faculty and staff in sponsored research administration and acts as the key point of entry to access your Universal Worklist, the Effort Certification Reporting Technology (ECRT) Management System, Grants Management Tab and Buy@Duke.	Everyone should have access to Duke@work. If you need help, contact your designated SAP administration with your department/unit.
AWARD & PROJECT END	**Grant Management Tab (via Duke@work Portal)** This is a primary resource for research administrators in their support of Sponsored Research Administration (SRA). This tab provides various reports and functional tools that are specific to sponsored research. The Grant Management tab includes many daily tools needed for a research administrator at Duke.	Users should request access to the Grants Management tab via their SAP Security Administrator.
	Universal Worklist The online inbox for reviewing and approving various transactions related to the spending of award funds on the projects in which you are assigned as a research administrator.	The Universal Worklist is a tab that can be found in Duke@work. If you need help, contact your designated SAP Administrator with our department/unit.

LIFE CYCLE STAGE	SYSTEM	WHERE TO FIND
AWARD & PROJECT MANAGEMENT	**Effort Certification & Reporting Technology (ECRT)** A web-based system that serves as the institution's effort reporting and certification tool for personnel paid on sponsored research projects. Each department will have two groups of ECRT users: Effort Coordinators, who are responsible for the final review and processing of completed effort statements. Certifiers (faculty and exempt staff) who are responsible for certifying their effort.	Questions regarding ECRT should be directed to ECRT-Support via email at ecrt_support@duke.edu.
AWARD & PROJECT END	**Buy@Duke** Duke's web-based e-procurement tool to procure goods and services supporting business at Duke.	Contact the Procurement Office (procurement@duke.edu) for assistance with issues related to.

UPDATE

AGM
New Program beginning in February. RCC will inform applicants tomorrow (January 27th) as to acceptance and class dates, starting in February 10th.

Continuing Education
Remember, continuing education is changing to credit hours to accommodate dedicated hours of learning as of July 1, 2017. Discussions underway to count external webinars. Also, RCC will be contacting individuals who presented sessions at the Symposium for interest in repeating these as continuing education opportunities for those who couldn't attend a specific session.

Mandatory Evaluations
Remember, evaluations for all RCC courses will begin as of July 1, 2017. Although these are currently optional, we appreciate feedback and encourage you to become accustomed to completing the evaluations now, as they will be mandatory for credit as of July 1, 2017.

RCC Alert
Supplemental information to communicate new items, information; The Grant Management Community News will continue as an every other month more detailed newsletter.

Duke FINANCIAL SERVICES | RESEARCH COSTING COMPLIANCE

RCC ALERT!

January 26, 2017

QUICKSTART

Scheduled to launch in Spring 2017, QuickStart is developed to provide grant management "onboarding" to new employees within the first 90 days of hire and current Duke employees not in the RACI HR classified positions for grant management, but are performing limited research management functions.

Program Details:

- ✓ Six on-demand, self-paced online training modules with references and step-by-step guides
- ✓ *Capstone Class* that provides "hands-on" experience in a limited number of basic grant activities
- ✓ Enables new grant managers to learn basic research management concepts and skills in advance of entering RAA
- ✓ Supports individuals who perform basic grant duties, but are not currently eligible for RAA

More Information Coming Soon!

AGM Announcement*

RCC is excited to announce a **completely revised** AGM curriculum scheduled to begin in **February 2017**! AGM enrollment is now open and we are accepting applications.

The AGM Program consists of five **required** courses and a final exam.

AGM Program Courses will include:

- ✓ Advanced Effort Management
- ✓ Case Studies in the Federal Regulatory Environment
- ✓ Complex Project Management: Pre-Award
- ✓ Complex Project Management: Post-Award
- ✓ Communication Strategies in Research Administration

Electives

RCC has added a new class for continuing education or as RAA Elective beginning in April 2017.

Class: Fellowship, Training & Career Awards

Details: Features best practices for management these types of award on both the pre and post-award side.

NOTE: If you have previously taken "Management of Training and Career Awards," this class offers additional information on fellowship applications and awards.

Click here to register in the LMS!

***AGM NOTE**: *RCC hopes to offer each of the AGM classes three times a year to accommodate certification requirements. These new classes may be used toward continuing education credit for anyone who holds a current AGM certification. Course descriptions and scheduling information can be found in LMS.*

Questions?

Please contact rcc-cert@duke.edu

Duke University School of Medicine

ClinicalTrials.gov Updates: NIH Policy

January 2017

Duke University School of Medicine

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

ClinicalTrials.gov currently lists 195,624 studies with locations in all 50 States and in 190 countries.

Text Size

Search for Studies

Example: "Heart attack" AND "Los Angeles"

Search

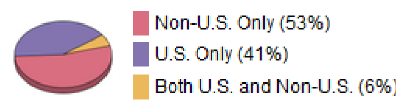
Advanced Search | See Studies by Topic

See Studies on a Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies



Total N = 36,338 studies
(Data as of July 30, 2015)

- See more trends, charts, and maps

For Patients and Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more…

For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more…

For Study Record Managers

- Why register?
- How to register your study
- FDAAA 801 requirements
- Learn more…

Learn More

- Tutorials for using ClinicalTrials.gov
- Glossary of common site terms
- For the Press
- Using our RSS Feeds

HOME | RSS FEEDS | SITE MAP | TERMS AND CONDITIONS | DISCLAIMER | CONTACT NLM HELP DESK

Duke University School of Medicine

DOCR’s Role

- Provide Support
  - System administrator for Duke since 2012
  - Assist with trial registration, results entry, and resolution of QA comments from ClinicalTrials.gov
- Offer Training
  - Introduction class and results entry workshop
  - Web-based Introduction class in 2017
- Monitor Compliance
  - Registration: review all new studies and manage approval for ACTs and qualifying trials
  - Results: track results due date based on dates provided by study team; send reminders to PI and regulatory staff
- Share Best Practices with CTSA Partners
  - REDCap tool; policies; resource allocation

CTSA PROFILE

ClinicalTrials.gov Reporting: Strategies for Success at an Academic Health Center

Erin K. O'Reilly, Ph.D., R.A.C.[1,2], Nancy J. Hassell, C.C.R.P.[3], Denise C. Snyder, M.S., R.D.[2,4], Susan Natoli, M.S.W., C.C.R.P.[2,4], Irwin Liu, Ph.D.[2,5,6], Jackie Rimmler, M.S.[2,5], Valerie Amspacher, B.S.[1,2], Bruce K. Burnett, Ph.D., R.A.C.[1,2], Amanda B. Parrish, Ph.D. R.A.C.[1,2], Jelena P. Berglund, Ph.D., R.A.C.[1,2], and Mark Stacy, M.D.[2,7]

Overview of Requirements

Requirement	Effective date	Scope
Applicable Clinical Trial (FDA-regulated products)	FDAAA: 2007 Final Rule: **1/18/2017**	Registration & results
Qualifying trial (billing insurance)	2015	Registration
ICMJE clinical trial (publication)	2005	Registration
NIH-funded clinical trials *New*	**1/18/2017**	Registration & results

Final NIH Policy

All NIH-funded clinical trials must be registered and have results reported in ClinicalTrials.gov

- NIH definition of “clinical trial” (**all** clinical trials, regardless of study phase or type of intervention)
- Grants, contracts submitted on or after the effective date
- Competing renewals that include a clinical trial initiated on or after the effective date

Effective Date: January 18, 2017

Duke University School of Medicine

NIH Policy Highlights

- Follow the same requirements and timelines as outlined in the regulations
  - Registration: Institutional approval will be held until the study is registered
  - Results: Due within one year of the Primary Completion Date
- As part of the application or proposal, submit a plan for how the expectations of the policy will be met
- Include a statement in the consent form

Final Rule: Key Changes

(apply to ACTs and NIH-funded trials)

- Full protocol and statistical analysis plan must be submitted and will be made public
- Defined deadlines for
  - Updates to registration information
  - Resolution of quality control comments from ClinicalTrials.gov
  - Results entry for secondary outcome measures

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Consequences of Noncompliance

- Suspension or termination of funding
- Can be considered in future funding decisions (for the grantee institution)
- Identifying clinical trial record as non-compliant in ClinicalTrials.gov

Workflow at Duke

Registration

- ACTs, NIH-funded clinical trials, and trials billing insurance are registered prior to DOCR approval in eIRB

Maintenance

- Monthly reports regarding outstanding items/errors

Results Entry

- Reminders prior to due date at 12, 6, 3, 2, and 1 months
- Defined escalation procedure

Duke University School of Medicine

Questions?

DOCR-CTgov@dm.duke.edu

Jessica Houlihan

Kristy Astin

Rebekah Davis

Jennifer Griffith

Susan Natoli

Duke University School of Medicine

GCP Training for NIH Funded Studies Update

Lorna N. Dula
Associate Director, Research Operations
DOCR Training and Communications

New Policy National Institutes of Health (NIH)

- Issued on September 16, 2016
  - NIH-funded investigators and staff should be trained in Good Clinical Practice (GCP) effective January 1, 2017.
  - This policy applies to all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical research.
  - Grace period extended till March 2, 2017

- CITI Program GCP courses meet the NIH Policy requirements
  - Meet the minimum criteria for ICH GCP Investigator Training identified by TransCelerate BioPharma.

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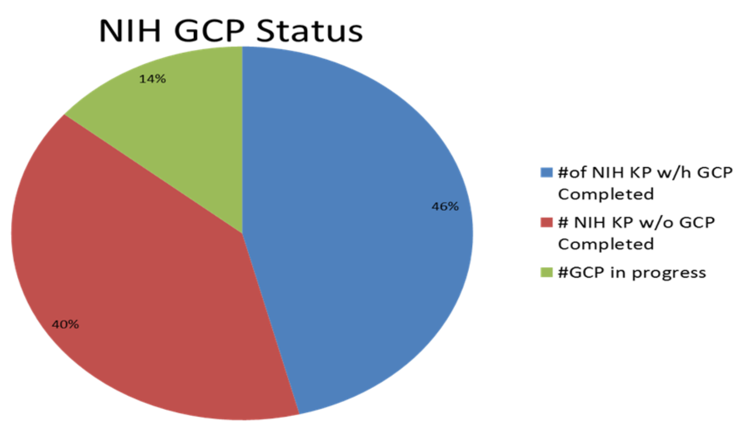
NIH GCP Status Update

- **Status as of January 22, 2017**: Completion data tracked indicates that we are overall 46% complete.
  - Completion of GCP Course = **completion of <u>all</u> modules of approved courses in CITI**
    - Total KP on NIH funded has changed over time as KP lists are modified
    - KP have been identified as having completed relevant training at other facilities
    - RPMs and DOCR communicating with staff and faculty



Challenges

Users have expressed dissatisfaction with taking the GCP modules

- Number of modules intimidating to some
- Hours of time to complete – several hours
- Accessing the modules difficult (we are restricted due to CITI program)
- Nature of CITI modules - all text - cumbersome

Administrative challenges maintaining update list due to:

- Ongoing removal of Key personnel from protocols
- Issue with CITI push for some members at refresher stage completion 3 and 4

GCP Training from other institutions accepted if Trancelerate approved

Overall everyone has communicated and has been cooperative

Next Steps - Path Forward

Task	Date started	Target Date Completion	Responsible
Increase frequency of updates to CRUs	1/9/2017	2/28/2017	DOCR
Contact individuals (KP) needing GCP	1/23/2017	1/23/2017	RPMs
CITI merge GCP and Biomedical Research - stand alone + Biomedical Research (admin task)	2/15/2017		DOCR/CITI
Obtain Administrative rights for DCRI and University Domains for tracking	2/1/2017		DOCR
Interface to LMS for transcript completion	2/1/2017		CITI/DOCR
Activate CITI Course change title –remove Basic Biomedical merge - admin task for uploading	2/28/17		CITI/DOCR
Duke Health researchers who are not on NIH studies will be required to take the CITI GCP module or renewal when current credentialing expires.	Ongoing	Ongoing	DOCR

Key Points

- International research definition
- Big ticket issues to keep in mind
- Special budget considerations
- Managing the post-award environment
- Communicating effectively with collaborators
- Q&A

What is International Sponsored Research?

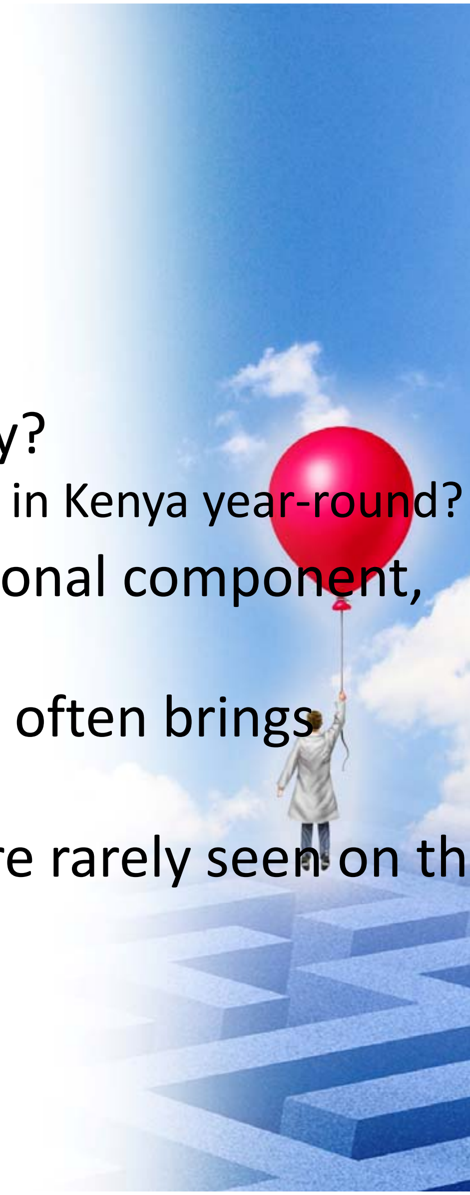
No simple definition

- Example: What if Duke PI travels internationally?
  - Is a conference in Switzerland the same as working in Kenya year-round?
- MOST research Duke does have some international component, however indirect

The reason that “international” matters is that it often brings complexity to a proposal/project

- Many issues faced in the international space are rarely seen on the domestic side

So what should you look for in a proposal?



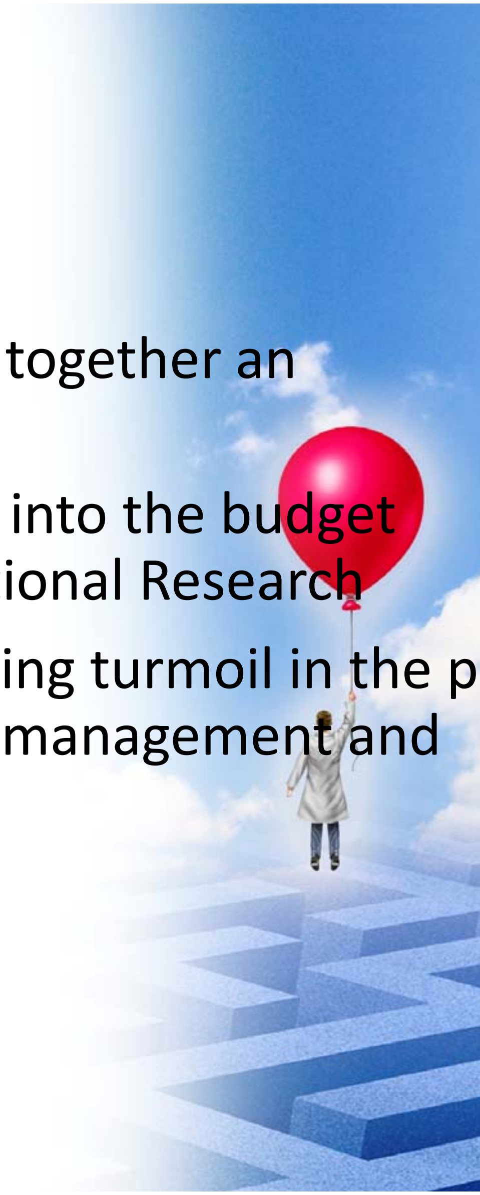
Does the proposal include?	Why this matters	Other issues to consider
Duke faculty/staff working at an international location ("boots on the ground")	1. Hiring local staff 2. HR, Tax, Legal requirements 3. Banking/payments	1. Length of stay (2 weeks versus 8 months) 2. Number of staff 3. Duke vs Non-Duke people 4. Conference? Business Meeting? L-T research?
Sponsor (or Prime) is an international entity	1. Foreign legal requirements 2. Agreement issues	1. Translation needed? 2. Might need Legal to weigh in
Human Subjects work and/or work with animals will be done outside the USA by Duke	1. Campus and SoM IRB are expert on US rules but not expert on the rules in all other countries	1. Will data (HS or otherwise) be sent back to USA?
Human Subjects work and/or work with animals will be done outside the USA by a third party (e.g., subawardee)	1. Duke must get IRB approval even if no Duke personnel engaged in HS 2. Some local partners may not have an IRB	1. Will data (HS or otherwise) be sent back to USA?

Does the proposal include?	Why this matters	Other issues to consider
Subawardees are international entities	1. If federal work, subs may need DUNS, SAM.gov, etc. 2. Some smaller subs may lack experience and need help budgeting, etc.	1. Has PI assessed whether sub has capacity to do the work (Technical? Financial?)
Duke is sending data or items/goods to international destination	1. Different rules on data privacy and security (EU)	
Duke is bringing tangible items from foreign site into USA	1. Could have customs issues 2. Animals/animal products	
Project involves foreign nationals coming to USA/Duke	1. Exposes Duke to liability 2. Foreign visitors may need help with visas, insurance, etc.	1. What is the nature of the visit? Lab work vs training course? 2. Short or long-term? 3. In-country logistics

How Can I Help?

- Make sure you always fill in the international sections of your SPS records
- Let your representative know as early in the process as you can – well before the proposal is routed – that your PI is planning on submitting an international proposal
- Make sure your PI is thinking about all international – related budget items
  - Security, tax, insurance, etc.

Budgets



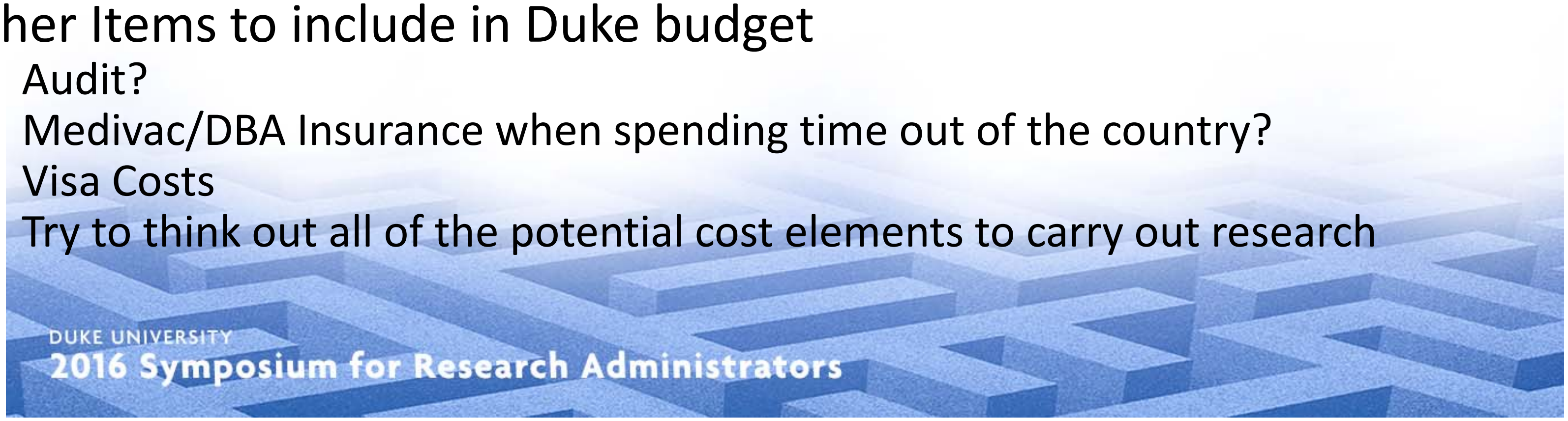
- Big-ticket issues to keep in mind when putting together an International Research proposal
- Special considerations that should be factored into the budget preparation process when conducting International Research
- Practices for effectively managing and minimizing turmoil in the post-award environment – both in terms of project management and financial management

Big-ticket Issues for Budgets

- Build enough time into the preparation process, in light of different time zones
- Factor in time to explain (to new sub-recipients) the process of getting DUNS numbers, FWA assurance, Animal Welfare Assurance, etc.
- Try to conceptualize the budget in terms of whether the costs should be part of Duke's budget or the budget of a sub-recipient How can the work best be accomplished by collaborators
- On-Campus vs. Off-Campus F&A rate

Special Considerations

- Duke costs or Sub-Contract/Award Costs?
  - Duke costs? If research is taking place in an off-campus environment over longer periods of time:
    - Pay for off-campus rent for facility?
    - Other costs – Electricity, Security, Telecommunications, Vehicle, Vehicle Maintenance?
  - Sub Costs
    - Make sure sub is building budget that is appropriate to the work that will take place
    - F&A Rate Agreement? If no, consider direct costing administrative items
    - Build wire fees into Duke budget to support the sending of wires to international partners
- Other Items to include in Duke budget
  - Audit?
  - Medivac/DBA Insurance when spending time out of the country?
  - Visa Costs
  - Try to think out all of the potential cost elements to carry out research



Practices for Post-Award Management

- Make sure budget set up in proposal process has thought through the post-award environment
- Contracts vs. Sub-contracts
  - Contracts – International RSSA vs. A/P Check Request
  - Sub-Contracts – required reporting and payment options
- Financial Reports for Sponsors
  - Sometimes the Grant Administrator and Program Team need to help OSP/TBS with financial reporting
  - Collecting revenue from certain foreign sponsors difficult sometimes
- Other items
  - Audit Risk for Subs → Collect all of the original receipts/documentation as possible
  - Fly America and Open Skies Agreement
  - Consider using International Per Diem when traveling, due to difficulty with collecting itemized receipts → Consider modified per diem
  - Be careful buying meals for collaborators when abroad, due to problems with reimbursement

What Should I Do?

- Let your RA/RAM/AD know
    - Important that your ORS/ORA representative is aware
    - RA/RAM/AD will contact me when needed
- Depending on the complexity of any particular international proposal:
    - I may serve as your ORS/ORA representative for the proposal;
    - I may work in tandem with your ORS/ORA representative (your representative will remain primary contact); or
    - Your ORS/ORA representative may handle the proposal, with me providing assistance to your representative as needed

ORA News and Reminders

Total Professional Effort (TPE) Reminder

- Statement regarding TPE must be included in ALL applications including Faculty <50% Duke appointment
- Calculator on ORA website
  - Auto calculates TPE %
  - Includes standard verbiage

ORA TPE CALCULATOR

FACULTY: Grant

TPE:	**DUKE**	**PDC**	**VA**	(3 sources combined must total 100%)
	40%	56%	4%	

% OF DUKE EFFORT ON PROJECT (enter from SPS salary worksheet)

20%

% OF TPE ON PROJECT

8%

This calculator is to be used for all Duke faculty that have reported a total professional effort (TPE) distribution of a less than 50% commitment to Duke University. It is critical that we clarify these situations in external proposals, to provide sponsors with a more complete perspective on our faculty members' commitment to the project than would be clear from the Duke effort percent alone.

Please complete the highlighted fields above, using the faculty member's last name; current TPE distribution between Duke, the PDC and the VA; and the % of their Duke effort committed to the project. The resulting statement listed below should be included in the budget justification for each faculty member with <50% TPE at Duke.

Dr. Grant 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.

Total Professional Effort (TPE) Reminder

FACULTY:	Grant			
TPE:	**DUKE**	**PDC**	**VA**	(3 sources combined must total 100%)
	40%	**56%**	**4%**	
% OF DUKE EFFORT ON PROJECT				(enter from SPS salary worksheet)
	20%			
% OF TPE ON PROJECT				
	8%			

Dr. Grant 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.

Employee Salary Request Form

- Dept. submitting the application is responsible for including TPE statement for all faculty with <50% appointments, regardless of PI's owning ORG
- Depts. need to communicate via Employee Salary Request Form if appointment is <50%
- https://medschool.duke.edu/sites/medschool.duke.edu/files/field/attachments/Salary_Request_Form.pdf

Employee Salary Request

(see next page for instructions)

Reset Form | Print Form

o Specify whether the individual has a Duke SOM appointment of less than 50% in the Salary Notes.

Personal Services Agreement (PSA)

- Revised "Duke as a Sponsor" and "Institute for Medical Research (IMR) as a Sponsor" forms
- Please use for all new, modified or extended PSAs
- https://medschool.duke.edu/research/research-support-offices/office-research-administration/va-partnerships/veterans-affairs-psas.

Personal Services Agreement

Part I – Nature of the Service Agreement ☐ **New Agreement** ☐ **Modification** ☐ **Extension**

Part II – Information on Participating Employee

2. Name (Last, First Middle)	3. Social Security Number:
4. Home Address (Street, City, State, ZIP)	

Foundation Exception Letter

- ORA includes Foundation Exception Letter with applications to sponsors who require Duke to sign off on terms and conditions with applications
- Typically non-profit sponsors
- Critical for maintaining Duke's ability to negotiate and accept the award
- Please be sure to include this letter in the application if the department is submitting the application

Duke University
Office of Research Administration
Telephone: (919) 684-5175
Facsimile: (919) 684-6278

January 19, 2017

To AANEM Foundation for Research & Education:

On behalf of Duke University, I am pleased to endorse the enclosed proposal submitted by [PI Name] titled [project title]. We have reviewed the proposal, and if the proposal is funded, we agree to administer the resulting award.

Please note that Duke University only conducts basic and applied research in science and engineering, the results of which are published and shared broadly within the scientific community. Final determination of what may be published or not published must remain with the university. Duke University cannot accept award terms which would violate our fundamental research status nor can we accept terms which would violate our University-Industry Guidelines, a copy of which is available at: http://provost.duke.edu/wp-content/uploads/FHB_App_P.pdf.

Duke University reserves the right to negotiate agreement terms if awarded.

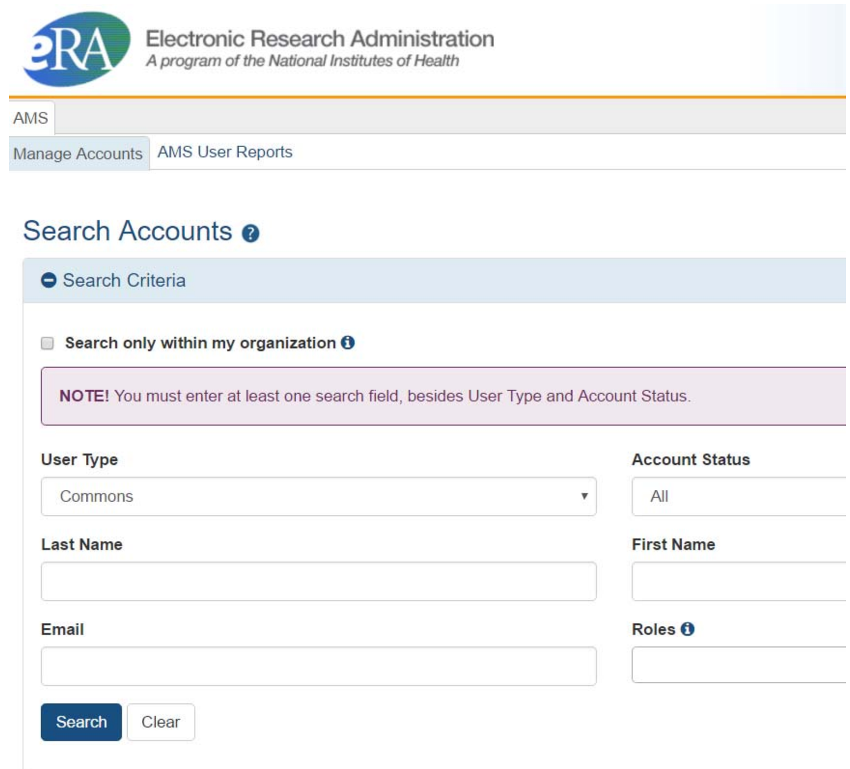
We look forward to this collaboration between our organizations.

Sincerely,

Signing Official
Duke University School of Medicine
Office of Research Administration
2200 West Main Street
Box 104008, Suite 820 Erwin Square
Durham, North Carolina 27705

Accounts Clean-up

- SPS Security Officer/eRA Commons AOs in departments are responsible for setting up SPS and eRA Commons accounts
- Department’s responsibility to keep accounts up to date
- We’re finding many old accounts still active in both systems
- ORA recommends annual review



ORA Signatures

- eRA Commons' Signing Officials have authority to submit prior approval and other official documents to GMS at NIH
- The 'Duke way' has been to include Director/Associate Director signature block on these
- If the SO is sending the request via email or eRA Commons to NIH, no additional signature is necessary

Sponsor Related News

Prior Approval for Fixed Price Subawards

- § 200.332 Fixed amount subawards require prior written approval from agency
- NIH is the only agency that provided a waiver to the requirement in an FAQ in Feb. 2015
- Updated NIH GPS (Oct. 2016) 8.1.2.11 now requires prior approval on NIH awards for fixed price subawards. Applies retroactively to grants with a budget period starting on or after October 1, 2016.
- COGR is asking for clarification, but as of Oct. 1, 2016, any fixed price subawards will need to have prior approval for each entity. At proposal stage, you can budget and make clear in the justification that it will be fixed price and that will be considered approval if awarded. Prior approval is not provided if you list the subs as TBD or fail to include language that your intent is to issue them as fixed price.

NIH application guide and supplemental instructions

- NOT-OD-17-023
- Minor changes to the layout and style of instructions
- New instructions are marked with this symbol
  - Hover over the icon in the web version to read an explanation of the change
  - The symbol will be visible in the PDF version, but will not display hover text
- Significant changes can be read here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.120-significant-changes.htm

How to Use the Application Instructions

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.100-how-to-use-the-application-instructions.htm

… and NSF PAPPG
Proposal & Award Policies & Procedures Guide

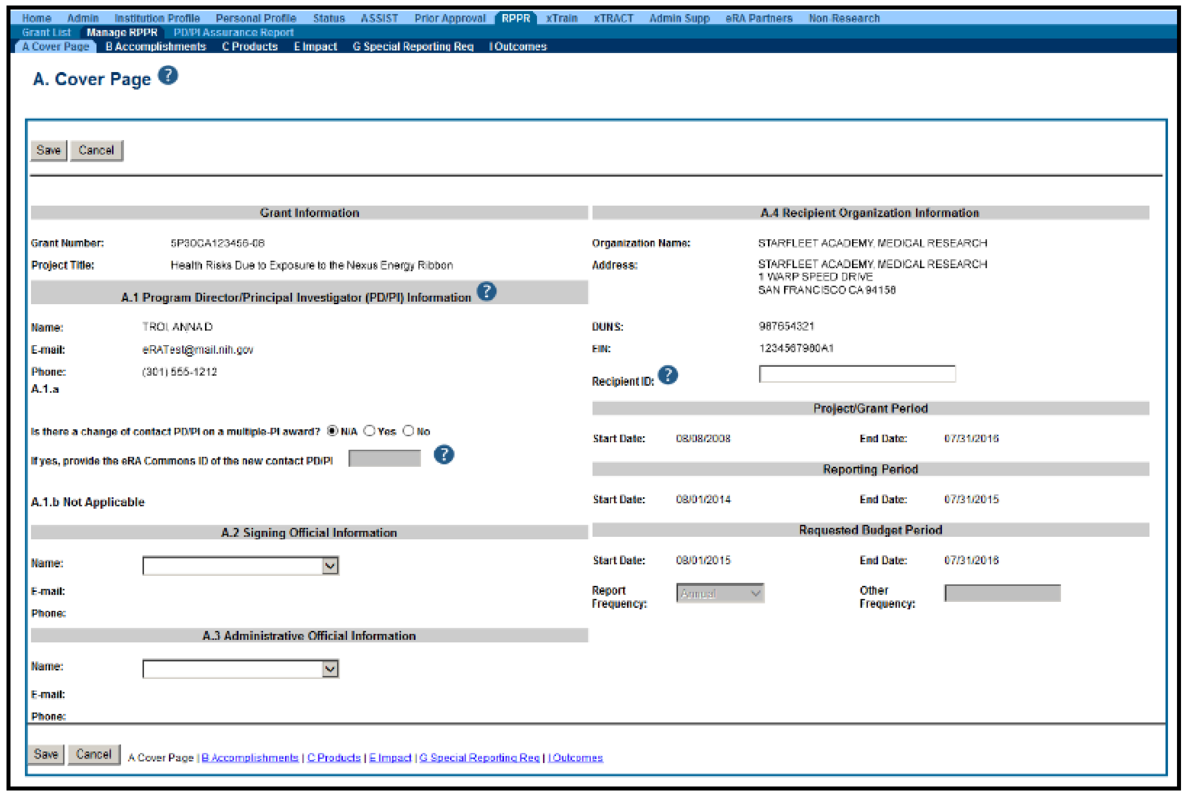
- https://www.nsf.gov/pubs/policydocs/pappg17_1/index.jsp
- Effective for proposals submitted or due, and awards made on or after, January 30, 2017
  - NSF Grants.gov application guide - https://www.nsf.gov/pubs/policydocs/grantsgovguide0117.pdf
  - Frequently Asked Questions (FAQs) On Proposal Preparation and Award Administration - https://www.nsf.gov/bfa/dias/policy/papp/pappg17_1/faqs17_1.pdf
  - NSF Award Terms and Conditions - https://www.nsf.gov/awards/managing/award_conditions.jsp?org=NSF

PCORI – New Version PCORI Online

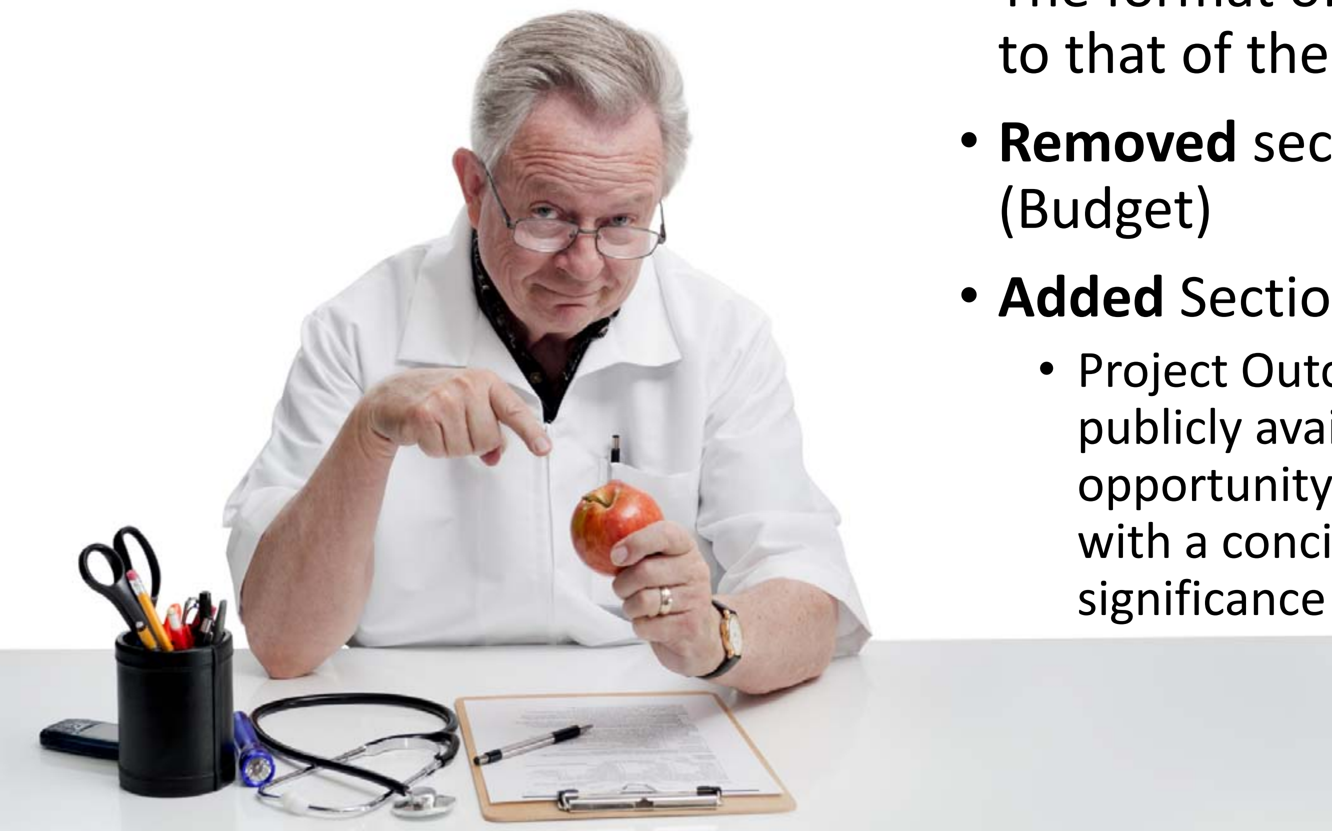
- Progress Reports must be submitted via PCORI Online effective Jan. 2nd
- All PCORI funding opportunities for Cycle 1 2017 onward will utilize the new PCORI Online including:
  - Submitting LOIs
  - Applications
  - PCORI Information Requests
- Applications being submitted for Cycle 3 2016 Funding Opportunities **will not** utilize the new PCORI Online
- User manual and recorded webinar training course that you will be able to access via PCORI.org coming soon!
- http://www.pcori.org/funding-opportunities/awardee-resources

NIH Implementation of Final Research Performance Progress Report (Final RPPR)

- NOT-OD-17-022
- Effective January 1, 2017
- The Final Research Performance Progress Report (F-RPPR) replaced the Final Progress Report (FPR) for grants closeout



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

The F-RPPR, in an ideal world…

STEP 1: Grant Manager (GM) engages with PI to ***review the PI's role*** in the financial closing out of the award, such as the ***importance of following deadlines*** when submitting the F-RPPR & signing the PI Attestation

GM engages with PI

PI works on final report

GM communicates name of ORA rep. for eRA Commons

STEP 2: PI begins to work on the F-RPPR while GM works on financially closing out the award (through the close out process, e.g. 60 days)

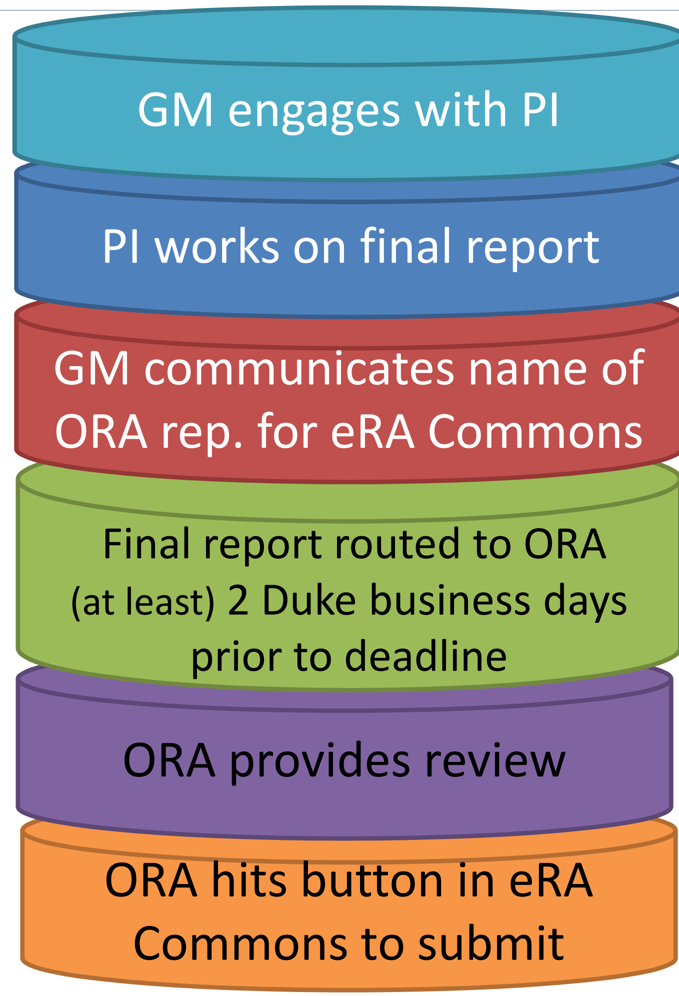
STEP 3: GM engages with PI for status updates including the F-RPPR ***& shares*** the name of the appropriate ORA representative for eRA Commons;

GM also ***communicates any exceptions*** to the process to ORA

STEP 4: PI selects ORA representative (dept. rep, not John or Michael) & routes; eRA Commons sends automated email to official to review

NOTE: No new SPS record or Admin Action Request is needed

STEP 5: ORA provides (minimal) review within 2 Duke business days



STEP 6: ORA submits the Final RPPR prior to day 90 (closeout)

The F-RPPR, in an ideal world…

Please remember

Validate each section for errors

RPPR Menu

Error Messages

Overall - Section A. Cover Page: (ID: 201309)
A.2. Personal Profile information for the Signing Official assigned to the RPPR has the following errors and must be corrected by the SO: Please complete Employments section in Commons Profile. (ID: 201295)
Overall - Section B. Accomplishments: (ID: 201315)
B.1. An answer is required. (ID: 201238)
B.2. An answer is required. (ID: 201240)
B.3. An answer is required. (ID: 201241)
B.4. An answer is required: select Nothing to Report or enter/upload response. (ID: 201243)
B.5. An answer is required: select Nothing to Report or enter/upload response. (ID: 201244)
B.6. An answer is required. (ID: 201245)
Overall - Section C. Products: (ID: 201316)
C.1 An answer is required. (ID: 201246)
C.2. An answer is required: select Nothing to Report or enter/upload response. (ID: 201247)
C.3. An answer is required: select Nothing to Report or enter/upload response. (ID: 201248)
C.4. An answer is required. (ID: 201249)
C.5. An answer is required: select Nothing to Report or enter/upload response. (ID: 207473)
Overall - Section D. Participants: (ID: 201317)
D.1. A required field is missing. (ID: 201257)
D.2.a. An answer is required. (ID: 201262)
D.2.b. An answer is required. (ID: 201263)
D.2.c. An answer is required. (ID: 201264)
D.2.d. An answer is required. (ID: 201265)
D.2.e. An answer is required. (ID: 201266)
Overall - Section E. Impact: (ID: 201318)
E.2. An answer is required: select Nothing to Report or enter/upload response (ID: 201267)
E.4. An answer is required: select Nothing to Report or enter/upload response (ID: 201268)
Overall - Section F. Change: (ID: 201319)
F.2. An answer is required: select Nothing to Report or enter/upload response. (ID: 201270)
F.3.a An answer is required: select No Change or enter/upload response. (ID: 201271)
F.3.b An answer is required: select No Change or enter/upload response. (ID: 201272)
F.3.c. An answer is required: select No Change or enter/upload response. (ID: 201273)
F.3.d. An answer is required: select No Change or enter/upload response. (ID: 201274)
Overall - Section G. Special Reporting Requirements: (ID: 201320)
G.1. An answer is required: select Nothing to Report or enter/upload response. (ID: 201275)
G.4.c. An answer is required. (ID: 201279)
G.5. An answer is required. (ID: 201280)
G.6. An answer is required. (ID: 201281)
G.9. An answer is required: select No Foreign Component or enter/upload response. (ID: 201283)
G.10. An answer is required. (ID: 201285)
G.11. An answer is required. (ID: 201288)

Warning Messages

G.4.b. Updates to inclusion data record(s) have not been made for record(s) # 1042143,1043711,1043712,1043713,1043714,1043715,1085160,1085161. If updates are needed, navigate to G.4.b of the RPPR to access the Inclusion Management System and update records. (ID: 206732)
G.4.b. No cumulative inclusion enrollment data has been provided for the record(s) # 165391,165392,165393,1043710,1062866,1062870,1062872. Is this correct? If enrollment has not begun, you may proceed and submit the RPPR. If enrollment has begun, navigate to section G.4.b of the RPPR to update inclusion data record(s) cumulative enrollment data. (ID: 206732)

Please remember to run validations and correct all errors prior to routing to ORA

Duke Office of Research Administration
Duke University School of Medicine

NIH Implementation of the Interim-RPPR while a Renewal Application is Under Consideration

- NIH NOT-OD-17-037
- Effective Feb. 9th
- Interim-RPPR utilized when competing renewals are submitted
- NIH will discontinue the policy for renewal applications whereby, “whether funded or not,” the progress report contained in the renewal application may serve in lieu of a separate final progress report
- An Interim-RPPR link for the grant will appear in the Status tab in eRA Commons after the period of performance end date has passed

NIH Implementation of the Interim-RPPR while a Renewal Application is Under Consideration

Scenario	Status of Competing Renewal Application	Workflow Process
1	Competing Renewal not submitted	Submit a Final-RPPR no later than 120 calendar days from the period of performance end date.
2	Competing Renewal submitted	Submit an Interim-RPPR no later than 120 calendar days from the period of performance end date. If the competing renewal is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.
3	Competing Renewal submitted but not funded	Submit an Interim-RPPR no later than 120 calendar days from the period of performance end date. If the competing renewal is not funded, NIH will treat the Interim-RPPR as the institution's Final-RPPR. To reduce burden NIH will not require recipients to submit an additional Final-RPPR if the renewal application is not funded.

NIH & AHRQ Update Font Guidelines

- NOT-OD-17-030
- **Text Color**: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.
- **Font size**: Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%.
- **Type density**: Must be no more than 15 characters per linear inch (including characters and spaces).
- **Line spacing**: Must be no more than six lines per vertical inch.
- **No restriction on font type –** though there are recommendations (Arial, Georgia, Helvetica, Palatino Linotype)

During an NIH NCE, is there a minimum effort requirement for key personnel named in the NOA, other than the PI?

NIH NCE Effort Requirement

- NIH GPS 8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds
  - NIH will not require prior approval for the reduction in effort for Senior/Key personnel named in the NOA. The recipient is reminded that active awards must have a measureable level of effort.
- NIH GPS 8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA
  - The recipient is required to submit a prior approval request to the GMO if the PD/PI or other Senior/Key Personnel specifically named in the NoA will:
    - Withdraw from the project entirely
    - 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

National Institutes of Health
Office of Extramural Research

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Posted on November 22, 2016 by NIH Staff

During a No-cost Extension, Is There a Minimum Effort Requirement for Key Personnel Named in the Notice of Award, Other than the PI?

With the exception of grant programs that have an effort requirement, or where terms and conditions prohibit such reductions, NIH will not require prior approval for the reduction in effort for Senior/key personnel named in the Notice of Award (NoA) during a no-cost extension. However, consistent with the NIH Grants Policy Statement Chapter 8.1.1.3, recipients are reminded that for active NIH awards, the PD/PI and other Senior/key personnel named in the NoA must devote a measurable level of effort.

Should vs. Must

Proposal Review Criteria

GENERAL INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES

SF424 (R&R) Application Packages

263 Pages

NIH GRANTS POLICY STATEMENT

U.S. Department of Health and Human Services

National Institutes of Health

393 Pages

PART 200—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS

149 Pages

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

Proposal Review Criteria

NIH - NEW Traditional- Application Re

ORA internal document only

Documents To Print	SPS#
Prepare Performance Metric Form after review (Print on Yellow Paper).	
Print SPS Web review copy and DPAF (non-signature pages).	
Print all internal documents.	
Print Solicitaiton/Guidelines/Instructions for this proposal.	
Print Grants.Duke appllication or Adobe Package (if unable to submit throug	

DPAF (page 1,2,3)

Items for Review	Yes	No	Not Requir
Is the Proposal Type marked as NEW?	☐	☐	☐
Is the F&A rate correct? Note the primary project location	☐	☐	☐

NIH - NEW Traditional- Application Re

ORA internal document only

Documents To Print	SPS#
Prepare Performance Metric Form after review (Print on Yellow Paper).	
Print SPS Web review copy and DPAF (non-signature pages).	
Print all internal documents.	
Print Solicitaiton/Guidelines/Instructions for this proposal.	
Print Grants.Duke appllication or Adobe Package (if unable to submit throug	

DPAF (page 1,2,3)

Items for Review	Yes	No	Not Require
Is the Proposal Type marked as NEW?	☐	☐	☐
Is the F&A rate correct? Note the primary project location	☐	☐	☐
Is the Indirect Cost base type listed as MTDC?	☐	☐	☐
Is the Agency Due Date correct?	☐	☐	☐
Does the project period match the FOA requirements?	☐	☐	☐
Is the Sponsor listed as NIH? (eg; **NOT** NIDA, NCI)	☐	☐	☐
Is the agency Due Date more than 7 business days away from PCA date? If no, department needs to request a waiver.	☐	☐	☐
Does the total dollar amount stay within the allowed amount listed in the FOA?	☐	☐	☐
Validate/Confirm the proposal activity - Is the ACTIVITY reasonable?	☐	☐	☐
Will there be any human subjects? If yes, is status "pending" listed?	☐	☐	☐
Will there be any animal research? If yes, is status "pending" listed?	☐	☐	☐
Are there any subawardees listed? If no, skip the next question. If yes, obtain documents from dept. Verify dates, dollars, effort, and protocol information. SOW, FCOI, Institutionally Approved document (e.g: Face Page, LOI), Budget, Budget Justification, Checklist.	☐	☐	☐
Will there be any cost sharing? If yes, note who will be receiving cost sharing. Manually list personnel on page 2.	☐	☐	☐
Has the Assurances and Approvals (DPAF) page been signed, checked, and dated? If COI is marked 'yes', send entire DPAF and Summary of Work to 'Duke Conflict of Interest (Duke Conflict of Interest Office <dukecoi@dm.duke.edu>)' office via email. Use e-mail template. Place copy of e-mail sent to Duke COI in file.	☐	☐	☐

SPS Web Review Copy

Items for Review	Yes	No	Not Require
Has the Response to an FOA section been filled in correctly?	☐	☐	☐
Are there Multiple PIs?	☐	☐	☐
Is the Commons username listed and active for any PD/PI? Log on to eRA Commons to check	☐	☐	☐
Is there a Multiple PI Plan attached in internal documents? It must be signed by PD/PI(s) and Chair(s). Make sure commons users names are listed for all PIs.	☐	☐	☐
Are the performance sites (including sub contract sites) listed?	☐	☐	☐
Has INV box been checked for at least PI?	☐	☐	☐
Are roles such as Consultant and Mentor listed in the OSC category?	☐	☐	☐

SPS Web Review Copy – Budget

Items for Review	Yes	No	Not Require
Are salary dollars exceeding NIH salary cap cost-shared?	☐	☐	☐
Is there measureable effort listed for all senior/key (Greater than zero)?	☐	☐	☐
Are all of the roles listed appropriate to the NIH guidelines? Note that "student" and clerical roles are not acceptable unless otherwise listed in the FOA If grad student is listed make sure tuition remission is included under other as "Tuition Remission".	☐	☐	☐
Items for Review	**Yes**	**No**	**Not Require**
Do categories contain suffcient or reasonable detail? Ie; "Supplies - $1200" should include itemization.	☐	☐	☐
Are all consultant costs provided with Consultant letters, which include dollars, hours, etc.?	☐	☐	☐
Are all of the costs listed allowable by NIH and by the specific FOA?	☐	☐	☐
Are there any subcontracts listed? Does amount listed in budget in SPS for Subrecipient(s) match what has been provided by Subreceipient?	☐	☐	☐
For each Subcontract package: is DUNS # present, dates for each budget period correct, make sure the each Senior/key person has measurable effort, match consortium amounts for each year to SPS, budget justification is a pdf.	☐	☐	☐
Does budget exceed $499,999 excluding subcontract indirect costs in any year? If yes, Is Sponsor authorization attached in Internal documents?	☐	☐	☐

SPS Web Review Copy – Budget Justification

Items for Review	Yes	No	Not Require
Are all costs listed in budget described (each year, each category, $ amounts) in the budget justification?	☐	☐	☐
Do personnel justifications include effort in person months? Do efforts match budget?	☐	☐	☐
Do justifications include salary cap statements, inflation statements, VA statements and/or PDC statements?	☐	☐	☐
Are there any subcontracts listed? Is the sponsor required justification for Subrecipient(s) included?	☐	☐	☐

Grants.Duke (or Adobe Package) Printout SF424 (R&R) - Cover Sheet

Items for Review	Yes	No	Not Require
Block 1. Is Type of Submission correct? (Application or Changed/Corrected)	☐	☐	☐
Block 4. Agency ID (if Resubmission, is correct ID showing)	☐	☐	☐

Guidelines and Policy

MIGHT SHOULD
Recommendations based on experience/guidelines

MUST
Requirements based on Duke/Sponsor policy

LESS RISK

Proposal

Risk

Award

MORE RISK

LESS RISK

Proposal

MIGHT SHOULD
Recommendations based on experience/guidelines

MUST
Requirements based on Duke/Sponsor policy

Award

MORE RISK

It Depends Matrix!

ORA/Dept. Relationship Status Matrix

LESS RISK

	MIGHT SHOULD Recommendations based on experience/guidelines	MUST Requirements based on Duke/Sponsor policy
Proposal	**It's All Fun and Games…** • Personnel Roles	**I'm Not Mad, Just Disappointed** • Cost Share
Award	**We Need to Talk** • Changes in scope	**That Escalated Quickly!** • Consultant vs. Sub

MORE RISK

Awards

The 'Time' is Right
Earliest Feb. 5^{th} Submission

- Earliest submission for R01 10/5 Deadline
- Date stamped from grants.duke

- None… so far

Earliest Nov. 5^{th} Submission

- Neurobiology
  - 10/28/16 @ 10:45AM
  - Dr. Stephen Lisberger
  - PAL: Cristy L. McGranahan

~~Can't~~ Can Make it On Time

- FY17 Quarter 2
- No Waivers
- Minimum 5 Submissions
- Immunology
  - 100% On-Time

Distinguished J.M. Teamwork Award

- Recognizes department for their outstanding commitment to teamwork
- Award seeks to perpetuate the excellence of colloaboration and support between central and department offices by recognizing and honoring qualities such as:
  - Generosity
  - Giving
  - …and incredible omelettes
- Otherwise known as the best attempt to bribe ORA!
- Psychiatry
  - Making us homemade breakfast never hurt anyone!

Professional Development and Training Update

Upcoming Training Opportunities - Conferences

- SRA NC Chapter Meeting
  - Winston-Salem, NC; March 17, 2017
- NCURA Region III
  - Savannah, GA; May 6-10, 2017
- SRA Southern/Midwest Section
  - Nashville, TN; May 7-10, 2017
- NIH Seminar
  - Chicago, IL; May, 2017

Duke Office of Research Administration
Duke University School of Medicine

Research Performance Progress Report (RPPRs) for NIH	Tuesday, January 31
NIH Application Development, Management & Resources – The FOA – Part 1 of 2	Tuesday, March 7
NIH Application Development, Management & Resources – The FOA – Part 2 of 2	Tuesday, March 21
NIH Application Development, Management & Resources – Building Your Basic Budget Part 1 of 2	Tuesday, April 18
NIH Application Development, Management & Resources – Building Your Basic Budget Part 2 of 2	Tuesday, April 25
NIH Application Development, Management & Resources – It's Just In Time & the Notice of Award	Tuesday, May 16

Duke Office of Research Administration
Duke University School of Medicine

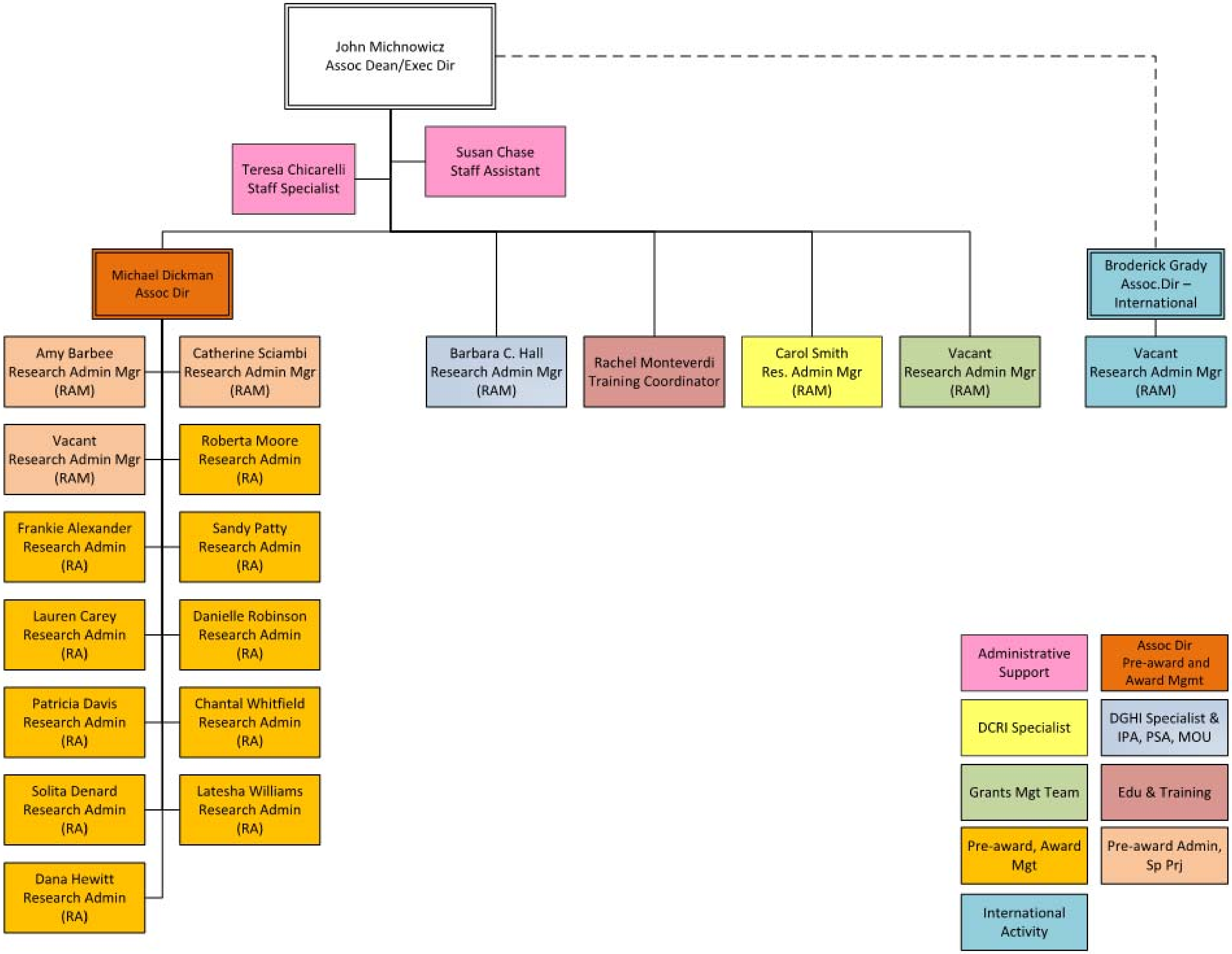
Sponsored Projects System (SPS): A Hands On Training	**Friday, May 26**
Other Support, Primarily for NIH	**Wednesday, June 7**
NIH Research Performance Progress Reports (RPPRs)	**Friday, June 16**
Intergovernmental Personnel Act (IPA) & the VA	**Wednesday, June 28**
Memorandums of Understanding (MOUs) & Personal Service Agreements (PSAs) for the VA	**Wednesday, July 12**
eSubmissions	**Wednesday, July 26**

ORA Staff Update

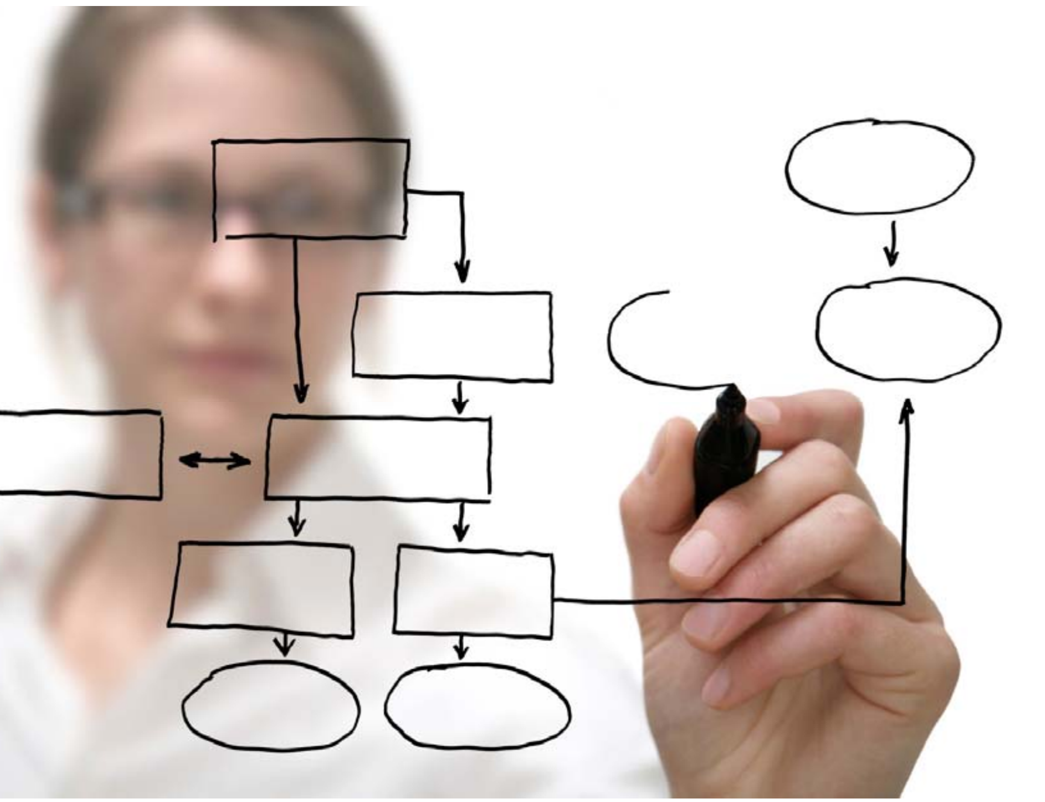
ORA Personnel Update

- Arrivals
  - n/a
- Openings
  - Research Administration Manager – Grants
  - Research Administration Manager – Grants Management Team (of 1)
  - Research Administration Manager - International
  - Research Administrator
- Departures
  - John DeFore
  - Latesha Williams

ORA Org Chart



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

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