Quarterly Administrator's Forum

Office of Research Administration September 2016

Agenda: Pre-Award division

- Updated Sponsor Policies for 2017
- Proposed OMB budget for FY 2017
- Hospital Signature process for Cost Share
- Clinical Trials new policies for 2017
- Clinical Trial account setup new processes
- FDA scheduled Investigator Training Session
- Personnel Updates
- PACS Update

New for 2017

Updated Sponsor Policies for 2017

NIH, AHRQ and NIOSH

- Beginning with ALL applications due on or after January 25, 2017
 - Change in allowable Post-Submission materials
 - Change in acceptable Appendix materials
- Application Guide and FOA's will be updated with new policies on November 25, 2016

- Reason for policy:
 - Simplify and consolidate current NIH and AHRQ policy and extend this policy to NIOSH
 - The only post-submission materials that will be accepted are those resulting from an unforeseen event
 - The policy is not intended to correct oversights/errors discovered after submission of the application

- Allowable Materials for ALL applications:
 - <u>Revised budget pages</u> due to institutional acquisition of equipment and/or new funding
 - <u>Biographical sketches</u> or <u>Letters of Support</u> due to a change in Senior Key Personnel (hiring, replacement or loss of investigator)
 - Adjustments resulting from <u>natural disasters</u> OR a <u>change in institution</u> of PD/PI and Senior/Key personnel
 - News of a professional promotion OR positive tenure in Senior Key Personnel
 - Approval by the NIH Stem Cell Registry about the creation of a new human embryonic cell line after submission

- Additional Allowable Materials:
 - <u>Videos</u>, within defined limits, that demonstrate devices and exploratory data (with a temporal element). See NOT-OD-12-141
 - News of an accepted article for publication, post submission. This may only include:
 - List of authors and institutional affiliations
 - Title of Article
 - Journal or Citation (if available)
 - Other materials as specified in the FOA

- Other materials related to an article such as:
 - copies of articles
 - links to articles
 - any other materials related to an article ...

will <u>not be accepted</u> as post-submission materials, unless specified in the FOA for which the application was submitted or a special Guide Notice

Additional Materials for Certain Applications:

- Institutional Training and Training-related Grants
- Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications
- Conference Grant Applications (R13, U13)

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-130.html

Requirements for submitting materials:

- All materials must conform to policies on font size, margins, and paper size
- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced apply
- Each item is limited to one page, unless it's specifically stated otherwise
- For applications with multiple components, each is allowed materials; however each is limited to one page

- Materials must be received no later than 30 calendar days prior to the peer review meeting.
 - If fewer than 30 calendar days remain, materials will <u>not</u> be accepted (unless specifically stated otherwise in the FOA)
- Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required - Sponsored Project Associate; Pre-Award
 - The AOR must submit the materials directly to the SRO; "cc" will not be accepted

Notice Number: NOT-OD-16-129 Updated Appendix Policy

Reason for policy:

- To rectify inequities in the peer review process that can arise from submission of inappropriate or excessive appendix materials
- To rectify consideration of appendix materials in peer review by some, but not all reviewers
- When submitting disallowed appendix materials:
 - "Applications will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required"

Notice Number: NOT-OD-16-129 Updated Appendix Policy

For ALL applications:

- ▶ The only allowable appendix materials will be:
 - Blank informed consent/assent forms
 - Blank surveys, questionnaires, data collection instruments
 - FOA-specified items

Notice Number: NOT-OD-16-129 Updated Appendix Policy

- For <u>clinical trials</u>, the following additional information is acceptable (unless the FOA states otherwise):
 - Clinical trial protocols
 - Investigator's brochure from Investigational New Drug (IND)

Office of Management & Budget

Proposed OMB budget for FY 2017

- The budgets are prepared based on the President's mission and Congress input
 - The budget invests in accelerating the pace of American innovation in order to create jobs, build the economy and tackle challenges
 - The budget invests in finding new treatments and cures for devastating diseases.

Prioritizing Research and Development

- An investment of \$152 billion for R&D overall through both discretionary and mandatory funding proposals, a 4% increase from 2016
 - Downstate has have active and pending awards because of this investment

- Support for Basic Research
 - The Budget provides \$14.6 billion in 2017, an increase of over \$900 million over the 2016 enacted level
 - Funds earmarked for the National Science Foundation, the Department of Energy's Office of Science, and the National Institute of Standards and Technology

- Advancing Biomedical Research
 - The Budget provides \$33.1 billion to support biomedical research for/at NIH
 - Funds providing approximately 10,000 new and competing NIH grants
 - Funds earmarked to understand the fundamental causes and mechanisms of disease, like the BRAIN Initiative and Precision Medicine Initiative (PMI)

Supporting a Cancer Moonshot

- \$1 billion initiative to provide the funding necessary for researchers to accelerate the development of new cancer detection and treatments
- Includes \$195 million in new cancer activities at the NIH in Fiscal Year 2016
- Includes \$755 million in mandatory funds in the 2017 Budget for new cancer-related research activities at both NIH and the FDA, and support from other agencies such as the DOD and Veterans Affairs

- Improving Access to High-Quality Child Care and Early Education
 - High-quality child care and early education for young children
 - Supports parents by allowing them to work while their children have access to education at an early stage
 - Supporting universal preschool
 - With the support of Federal funding made available, 18
 States are currently developing and expanding high-quality preschool programs in targeted, high-need communities

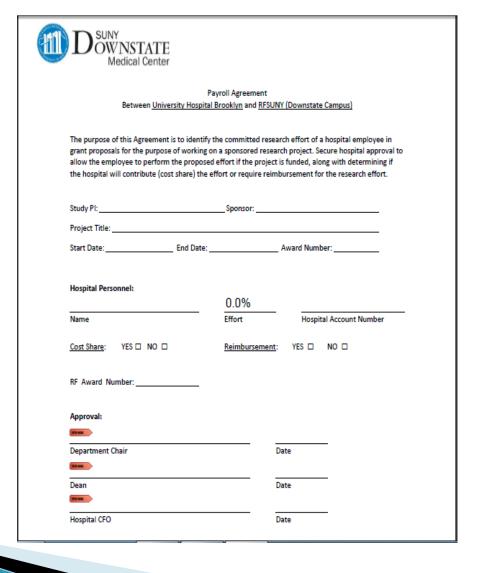
Cost Share with Hospital Personnel

Hospital Signature process

Cost-Share and the Hospital signature process

- Applicable when the cost-share is for a Hospital employee
 - Award number starts with a "3"
 - Award number is provided by the Department
- The Hospital CFO will sign in addition to the Dean and Department Chair
- All RF and Downstate policies remain the same

Hospital Cost-Share Form



CT updates for 2017

Clinical Trials - new policies for 2017

Clinical Trials - new Federal policy

- New DHHS regulation and NIH policy will be in effect as of January 18, 2017
- This will affect all NIH-funded clinical trials
- Initiatives aim to increase the availability of information to the public about clinical trials – information that is not systematically available from other public sources
- The Food and Drug Administration Amendments Act (FDAAA) expands <u>ClinicalTrials.gov</u> and imposes new requirements that apply to certain trials supported by NIH funds

FDAAA and Clinical Trials supported by NIH

- Trials subject to FDAAA are called "Applicable Clinical Trials" (ACT) and must be in full compliance with FDAAA
- Applicable Clinical Trials include:
 - Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation
 - Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post market surveillance

The Final Rule...

- Applies to the <u>Responsible Party</u> for <u>Applicable</u> <u>Clinical Trials</u> (ACTs)
 - The Responsible Party is the sponsor of a CT or a designated PI
 - An <u>Applicable Clinical Trial</u> must meet 1 or more of the following criteria:
 - The CT must include one or more sites in the United States
 - Must study a drug, biological, or device product that is manufactured in the United States or its territories
 - Is exported for use in CTs outside the United States OR must
 - Be conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE)

The Final Rule requires ...

- A responsible party:
 - must register an Applicable Clinical Trial in ClinicalTrials.gov
 no later than 21 days after enrolling the first participant
 - must submit summary results information to ClinicalTrials.gov regardless of whether the drug, biological, or device products under study have been approved, licensed, or cleared for marketing by the FDA
 - must submit information no later than 1 year after the primary completion date of the clinical trial

The Final Rule ... and NIH

- The final NIH Policy complements the Final Rule in that the NIH Policy applies to ALL clinical trials funded in whole or in part by NIH, regardless of the study phase, the type of intervention, or whether the clinical trial is subject to the Final Rule
 - Includes Phase 1 trials of drug and biological products, small feasibility studies of device products, and clinical trials of behavioral, surgical, and other types of health and medical interventions

Compliance to the Final Rule

- A responsible party has 90 days (3 months) <u>after</u> January 18, 2017 to come into compliance - no later than April 18, 2017
- NIH is required to make a responsible party's non-compliance public through a posting on the clinical trial record
- The FDA has the authority to issue a Notice of Noncompliance to a responsible party who has failed to comply
- A responsible party who commits a prohibited act(s) may be the subject of an injunction action or criminal prosecution brought by the Department of Justice
- Compliance with the NIH policy will be via the terms and conditions of the NIH award

Account Setup - Clinical Trials

Clinical Trial account setup - new processes

Account Setup for Clinical Trials

- We will upload the budget into Oracle, our financial system, in stages, depending upon the terms and conditions of the contract
- PI's responsibility not to exceed contractual amount
 - <u>Fixed price</u> contract, the budget for the fixed price will be uploaded
 - Milestone driven contract: An initial budget will be established for 20% PLUS any invoiceable items (IRB, startup, pharmacy, etc.) The initial 20% will be deducted from the final scheduled payments
 - <u>Capitation</u> contracts or per patient: An initial budget will be established for 20% <u>PLUS</u> any invoiceable items (IRB, startup, pharmacy, etc.) The initial budget of 20% will be deducted from the final per patient payments

FDA Investigator Training in November 2016

- ▶ FDA is offering a FREE, 3-day training session
 - The training course is for clinical investigators, such as clinicians, nurses, pharmacists and other health care providers involved in conducting clinical trials
 - Intended to provide investigators with the expertise in the design, conduct and analysis of clinical trials, and to enhance the safety of trial participants
 - Course runs from November 7–9: must register https://www.federalregister/gov/d/2016–22348

Personnel Updates

- Current positions posted:
 - Assistant Director
 - Sponsored Projects Associate (sPA)

Pre-Award Personnel Updates

New Hire for the Assistant Director position

Posting available for a Sponsored Project Associate (sPA)

Department Assignments will be revised accordingly

PACS Update

The Pre-Award Compliance System

Implementation by all campuses

PACS Update; Huron "Click"

- Pre-Award Compliance System (PACS) is a Grants Management System (GMS)
- Live Demos on all campuses in Summer 2015
- Purchased by the RF in December 2015
- 6 modules purchased:
 - Agreements / Safety / IACUC/ IRB / Grants/ COI
- 2 campuses are live with some of the modules

PACS: Agreements Module

- Harmonization Process and Testing is complete
- Determining "go-live" date
- Does not require faculty data entry
- Provides full transparency on status of negotiation
- Integration with other modules in Fall/Winter 2017

PACS: IRB Module

- Harmonization Process and Testing is complete
- Vendor is fixing "critical issues"
- Go-live date is scheduled for Fall/Winter 2017
- Expected integration with other modules at "go-live" stage

PACS: Grants Module

- Harmonization Process is Complete
- Testing has just begun
 - "Critical" issues will be fixed by vendor
- "Go-live" is expected Fall/Winter 2017
- Integration with other modules
- Routing process will happen within the system
 - Eliminate Proposal Tracking/Signature Worksheet
 - Eliminate Cost Share Template

PACS: IACUC Module

- Harmonization is complete
- Currently in Development
- "Go-live" is scheduled for Fall/Winter 2017
- Integration with other modules

PACS: Safety Module

- Harmonization is complete
- Testing Phase is set to begin
- "Go-Live" will be in Fall/Winter 2017
- Integration with all modules

PACS: COI Module

- Harmonization is complete
- Module is back with vendor for additional customization
- "Go-live" is scheduled for Fall/Winter 2017
- Integration with other modules

Agenda: Post-Award division

- Effort Reporting New for 2017
- Purchasing Service Agreements: Contractor requirements
- Online Purchasing (P-Cards)
- MWBE requirements
- FLSA
- Personnel Updates

E-Cert: Effort Certification

Effort Certification

Effort Certification

- It's a federal requirement that all persons working on a federal project commit and certify their effort semi-annually
- ► The results are audited annually as part of the A-133 audit report
- Commencing 7/1/16, non-exempt employees will <u>now</u> be included in this requirement

E-Certification, January-June

E-Cert 1/1/2015-6/30/2015 DUE 9/30/2015					
Department Name	C =	Pending		% Certified	% Not
Department Name		Certification			
100 Anatomy – Health Prof	1		0		
100 Anatomy – Medicine	6			100%	
100 Anesthesiology	1		0		
100 Assoc Dean-Minority Affairs College of Medicine	2		0	100%	
100 Biochemistry – Medicine	6		2	75%	
100 Cell Biology	13		0	100%	
100 Dean's Office - School of Public Health	1		0	100%	0%
100 Department of Environmental and Occupational	,		_	1000/	20/
Health Sciences	1		0	100%	
100 Department of Epidemiology	0		0	5 40/	100%
100 General Practice	9		5	64%	
100 Medicine	38		1	97%	-,-
100 Microbiology – Medicine	3		1	75%	/-
100 Neurology	15		0	100%	
100 Obstetrics&Gynecology	3		0	100%	
100 Opthalmology	3		0	100%	-,-
100 Pathology – Medicine	2		0	100%	
100 Pediatrics	14		1	93%	7%
100 Pharmacology	9		0	100%	0%
100 Physiology – Medicine	10		0	100%	0%
100 Physiology&Pharmacology	2		0	100%	0%
100 Preventive Medicine	20		0	100%	0%
100 Provost	0		0		100%
100 Psychiatry	43		9	83%	17%
100 Radiation Therapy	0		0		100%
100 SUNY IFR Cost Sharing	14		1	93%	7%
100 School of Graduate Studies	1		0	100%	0%
100 Sr VP Biomedical Ed&Res/Dean - College of					
Medicine	2		0	100%	0%
100 Star Program	6		0	100%	0%
100 Surgery	0		0		100%
100 VP for Biotechnology and Scientific Affairs	0		0		100%
100 VP for Hospital Affairs&CEO	0		0		100%
	225		22	91%	9%

E-Certification, July-December

E-Cert 7/1/2015-12/31/15 DUE 3/31/2016				
Department Name	Pendin Certified Certific		% No d Certi	
100 Anatomy – Health Prof	1	.ation % Certifie 0	100%	0%
•	1	2	75%	25%
100 Anatomy – Medicine	6			
100 Anesthesiology	0	1	0%	100%
100 Assoc Dean-Minority Affairs College of Medicine	1	0	100%	0%
100 Biochemistry – Medicine	4	l -	80%	20%
100 Cell Biology	14	1	93%	7%
100 Department of Environmental and Occupational Health Sciences	1	0	100%	0%
100 Department of Epidemiology	0	0		100%
100 Dermatology	0	1	0%	100%
100 General Practice	6	6	50%	50%
100 Institute for Genomic Health	0	4	0%	100%
100 Medicine	31	8	79%	21%
100 Microbiology – Medicine	4	1	80%	20%
100 Neurology	10	1	91%	9%
100 Obstetrics&Gynecology	3	0	100%	0%
100 Opthalmology	0	2	0%	100%
100 Pathology – Medicine	2	0	100%	0%
100 Pediatrics	9	6	60%	40%
100 Pharmacology	8	0	100%	0%
100 Physiology – Medicine	10	3	77%	23%
100 Physiology&Pharmacology	1	0	100%	0%
100 Preventive Medicine	19	0	100%	0%
100 Psychiatry	20	29	41%	59%
100 SUNY IFR Cost Sharing	14	3	82%	18%
100 School of Graduate Studies	1	0	100%	0%
100 Sr VP Biomedical Ed& amp; Res/Dean - College of				
Medicine	2	0	100%	0%
100 Star Program	6	0	100%	0%
100 Surgery	0	0		100%
100 VP for Biotechnology and Scientific Affairs	0	0		100%
	173	69	71%	29%

Purchase Service Agreements

Contract Requirements

Purchase Service Agreements

- Service Agreements must now include the following language:
- Statutory NYS Limits for Employers' Liability now requires a minimum limit of \$1,000,000 for Workers' Compensation (including occupational disease) and Employer's Liability. If contractor is a sole proprietor, submit a Workers Compensation Exemption Certificate, CE-200. The CE-200 can be obtained from the Workers Compensation Board website
- Disability Benefit Insurance as mandated by State law. If contractor is a sole proprietor, please submit a Workers Compensation Exemption Certificate, CE-200. The CE-200 can be obtained from the Workers Compensation Board website.
- Commercial General Liability: Bodily injury, Personal Injury, and Property Damage with minimum limit of minimum limit of \$1,000,000 per occurrence and \$3,000,000 aggregate. Limit may be provided through a combination of primary and umbrella/excess liability policies;
- Auto Liability (if applicable): \$1,000,000 combined single limit Bodily Injury/Property Damage per each accident (including owned, hired, leased and non-owned autos);
- Professional Liability (medical care, if applicable): Limits of liability greater than \$1,000,000 each claim and \$3,000,000 aggregate.

Purchase Service Agreement

- Department should complete the "Independent Contractor Services" form and send to Vendor for signature
- Completed form should be submitted to the Grant Manager for review against application budget.
 - Discuss rebudgeting options, if applicable
- Once approved, the Grant Manager submits to Purchasing for completion of contract and the creation of Purchase Order

Online Purchasing

P-Cards

Credit Card for Purchases

Online Purchase with a P-card

- For the purpose of purchasing items on-line with credit cards
 - Must have an award with an "Active" or "At-Risk" status
 - Must send Purchase Requisition to the Procurement Manager, indicating a "P-Card" requisition
 - Reviewed by Grants Manager to determine monies available and expense is "allowable," "allocable," and "reasonable"
 - Once approved, Purchasing will order the item with an RF credit card, specifically for these purchases
 - Department is still responsible for initialing the "blue" copy of the PO confirming receipt
 - Purchasing will apply the associated costs to the "Active" or "At-Risk" award

Online Purchase with a P-card

- New for 2017: Possible relationship with <u>Amazon</u> <u>Business</u>
 - The Procurement group within RF will open an Amazon Business account
 - Will appoint "requisitioners" throughout the Downstate system who will be authorized to make purchases using the RF account
 - Will be appointed by the RF to PD/PI's or their designees
 - These purchase will automatically flow to Procurement for approval
 - No purchase requisition will be required

NYS Minority and Women Business Enterprise (MWBE)

- We are in receipt of many NYS contracts that require MBWE certification
- Certification is based on OTPS dollars solely
- A certain percentage of the budgeted costs <u>must</u> be purchased from businesses that are either certified as minority owned or women owned
- The percentage is typically 15% minority and 15% women for a total of 30% of expenditures purchased from a certified vendor

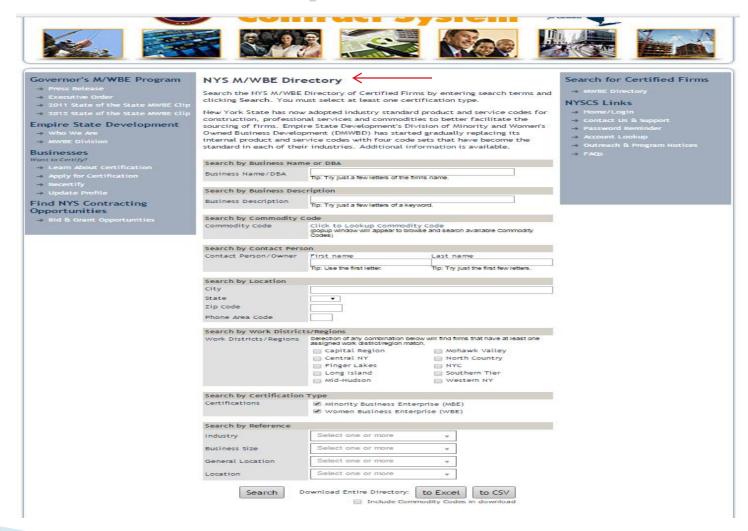
MWBE - at time of submission

- Responsibility is with the PD/PI to determine what OTPS costs can be purchased with vendors meeting this criteria
 - Form is required as part of the application
- PD/PI can hand pick these vendors by going to the MWBE website

MWBE website



MWBE directory



MWBE requirements

- If there's a specific reason why an MWBE vendor cannot be chosen, an explanation must be provided at the time of proposal on the MWBE form
- For these applications, a budget must be reviewed by the Director of Post-Award in order to prepare this form
- The form is required as part of the application and therefore will be considered incomplete if it is required and missing

Fair Labor Standards Act - FLSA

New FLSA Ruling and Requirements

FLSA Change

- The current dollar threshold for determining exempt status is \$23,660.00 per year
- This rate is not affected by whether or not an employee is full time or part time
- Effective December 1, 2016, the dollar threshold for determining exempt status will go up to \$47,476.00 per year
- This means that anyone earning less than \$47,476.00 per year regardless of their full time equivalency (FTE) will be considered nonexempt and as such eligible for overtime

Post Award; Personnel Update

Changes to Post-Award personnel

Personnel Updates; Post-Award

Posting for a Grants Manager

Redistribution of Departmental Assignments