

Research Administration and Compliance Meeting
September 21, 2011
1:00 – 3:00 p.m.
Larrick Hall

Agenda

Welcome

Staff Updates and Introductions

General Items/Updates

- Office of Research Reorganization
- Research Dashboard Project – Patricia Perkins
- Required Training – Investigator and Administrator Training – Susan Robb/Mark Roberts

G&C/Effort Reporting Updates – Mark Roberts

CRSO Updates – Tammy Anderson

Financial Conflict of Interest Update – Susan Robb

OSP Updates

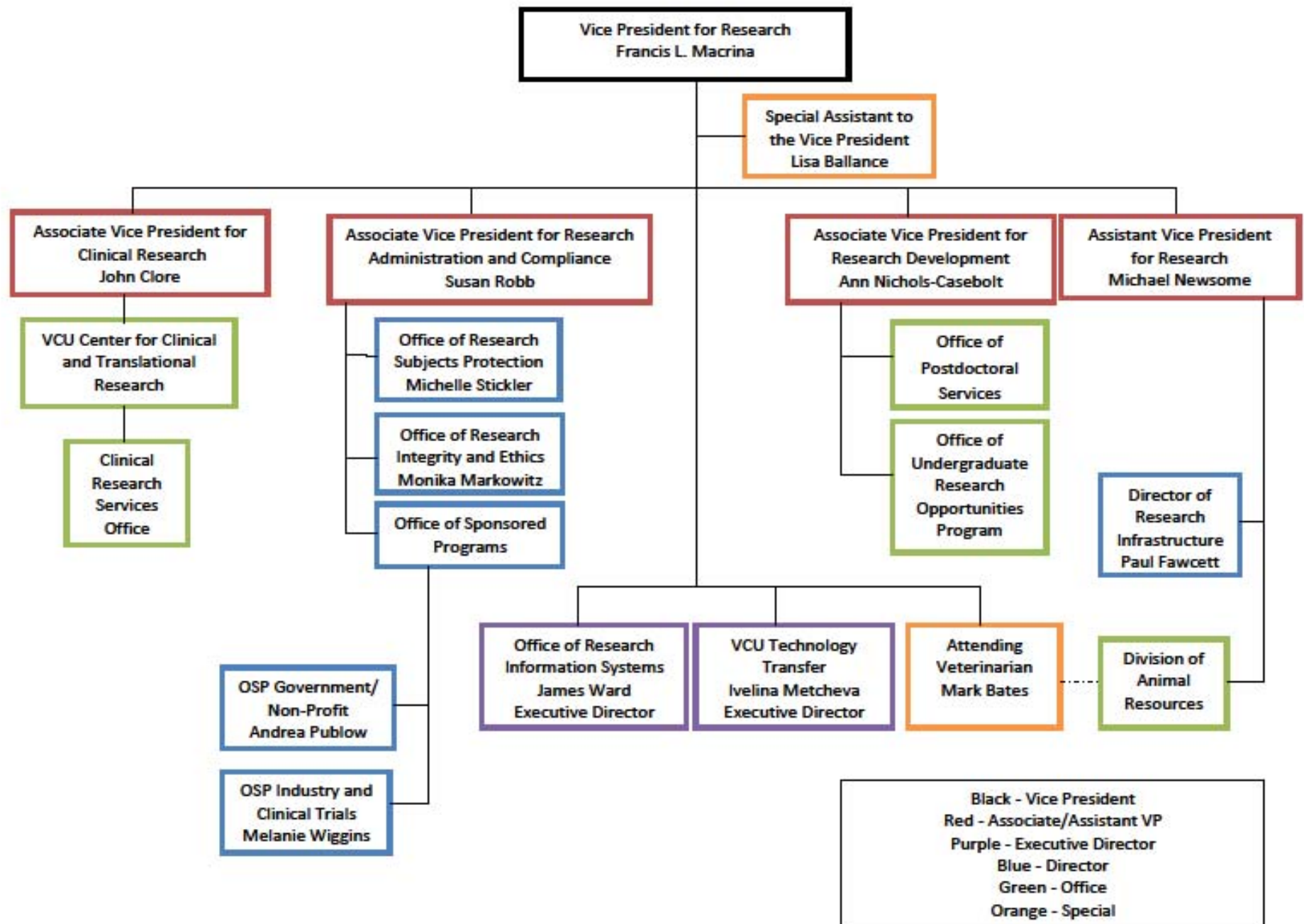
- Summer CleanUp Project Update – Annie Publow
- VCUeRA Workflow Update – Annie Publow
- Clinical Trial Agreement Prereview Process – Melanie Wiggins
- Clinical Trials.gov – Melanie Wiggins
- Certification Program – Annie Publow

September 2011

Office of Research Reorganization



V i r g i n i a C o m m o n w e a l t h U n i v e r s i t y



Research Compliance Program

- **Awareness, education, and training**
Communicating standards, procedures, and responsibilities to researchers, administrators, and others through timely and appropriate education and training
- **Communication**
Developing and maintaining effective systems of communication, including resources for promptly responding to compliance questions or concerns
- **Monitoring and audits**
Implementing monitoring and auditing systems to assure compliance, detect breakdowns, and identify potential problem areas
- **Policies and procedures**
Designing standards and policies that effectively enable researchers and others to meet compliance requirements

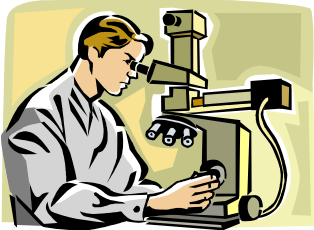
Research Compliance Program

- **Program Oversight**
Assuring compliance through senior leadership and independent oversight
- **Risk assessment**
Examining research activities regularly to identify and reduce potential compliance breakdowns
- **Enforcement and corrective action**
Enforcing standards fairly and consistently; promptly investigating and resolving compliance breakdowns; evaluating and modifying the compliance program where appropriate to prevent similar problems
- **Roles and responsibilities**
Maintaining clear roles and compliance responsibilities for all parties; using due care and appropriate oversight when assigning compliance responsibilities

FCOI Regulations - Final Rule

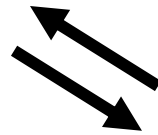
- Revising the regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*
- Federal Register published August 25, 2011
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
(this link points to a non-HHS website which may not be accessible to all visitors)
- Implementation no later than 365 days after publication of the final rule in the Federal Register, i.e. August 24, 2012. In the interim:
 - Institutions comply with 1995 regulations
 - Institutions revise policies, establish procedures for compliance, and train Investigators
 - NIH provides training materials for extramural community and NIH staff, expands FCOI reports database
- Basic framework remains the same

FCOI Regulations Framework



Investigator

Disclosure of SFI
Compliance with Institutional Policy

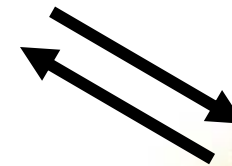


Institutional Policy
Implementation
Evaluation of SFI
Identification of FCOI
Management



Institution

Compliance with Regulations
Reporting to NIH



Oversight

NIH



Major Areas Addressed in the Revised Regulations

- Definition of Significant Financial Interest (SFI)
- Extent of Investigator Disclosure
- Information Reported to PHS Awarding Component (e.g. NIH)
- Information made accessible to the public
- Investigator Training

Major Changes to the Regulations I

- Significant Financial Interest (SFI)
 - Minimum threshold of \$5,000 generally applies to payments **and/or** equity interests
 - Includes **any** equity interest in non-publicly traded entities
 - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an Institution of higher education.
 - Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- Investigator Disclosure
 - All SFIs related to Investigators' **institutional responsibilities**
 - Institutions responsible for determining whether SFIs relate to PHS-funded research and are financial conflicts of interest (FCOI)

Major Changes to the Regulations II

- Reporting to PHS Awarding Component (NIH)
 - Previous requirements, (grant/contract number, name of PD/PI, name of Investigator with FCOI) plus:
 - **Name** of the entity with which the Investigator has a FCOI
 - **Value** of the financial interest
 - **Nature of FCOI**, e.g. equity, consulting fees, honoraria
 - A description of how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research
 - Key elements of the Institution's **management plan**
- Public Notice
 - Before spending funds for PHS-supported research, an Institution shall ensure public accessibility of information on certain SFIs that the Institution has determined are related to the PHS-funded research and are FCOI, via a publicly accessible Web site **or** by a written response to any requestor.
- Investigator Training
 - **FCOI training required** for Investigators before engaging in PHS-funded research, every four years thereafter, and immediately under designated circumstances.

Resources

- Mailbox for inquiries
 - FCOICompliance@mail.nih.gov
 - OER FCOI Web Site
 - <http://grants.nih.gov/grants/policy/coi/>
- New FAQs and tutorial coming soon

VCU
Office of Sponsored Programs
Office of Research

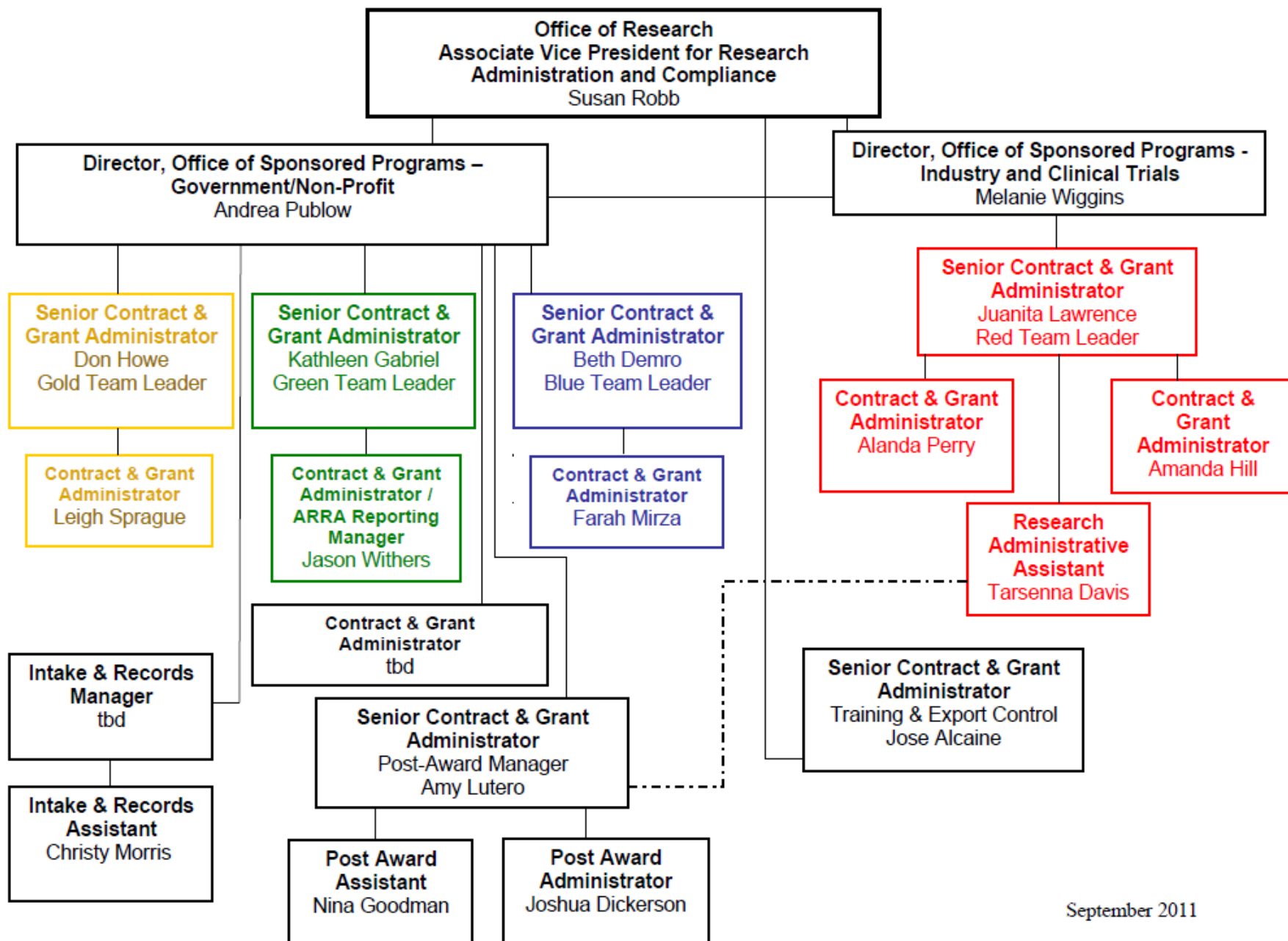


Committee on the Administration of Research's
Research Administration and Compliance Meeting
OSP Updates: Workflow and Closeout
Annie Publow, Director of Sponsored Programs,
Government/NonProfit Support
September 21, 2011

VCUeRA Workflow and Closeout Update

Presentation Topics:

- OSP-Government/NonProfit Staffing Updates
- VCUeRA Workflow and Closeout
 - Progress to date
 - Updated Phase Five Diagram and Definitions
 - Closeout of Older Awards
 - Closeout of “Not Awarded” Proposals
 - Updated Phase Zero Diagram and Definitions
- Sponsored Project Administration Certification Program



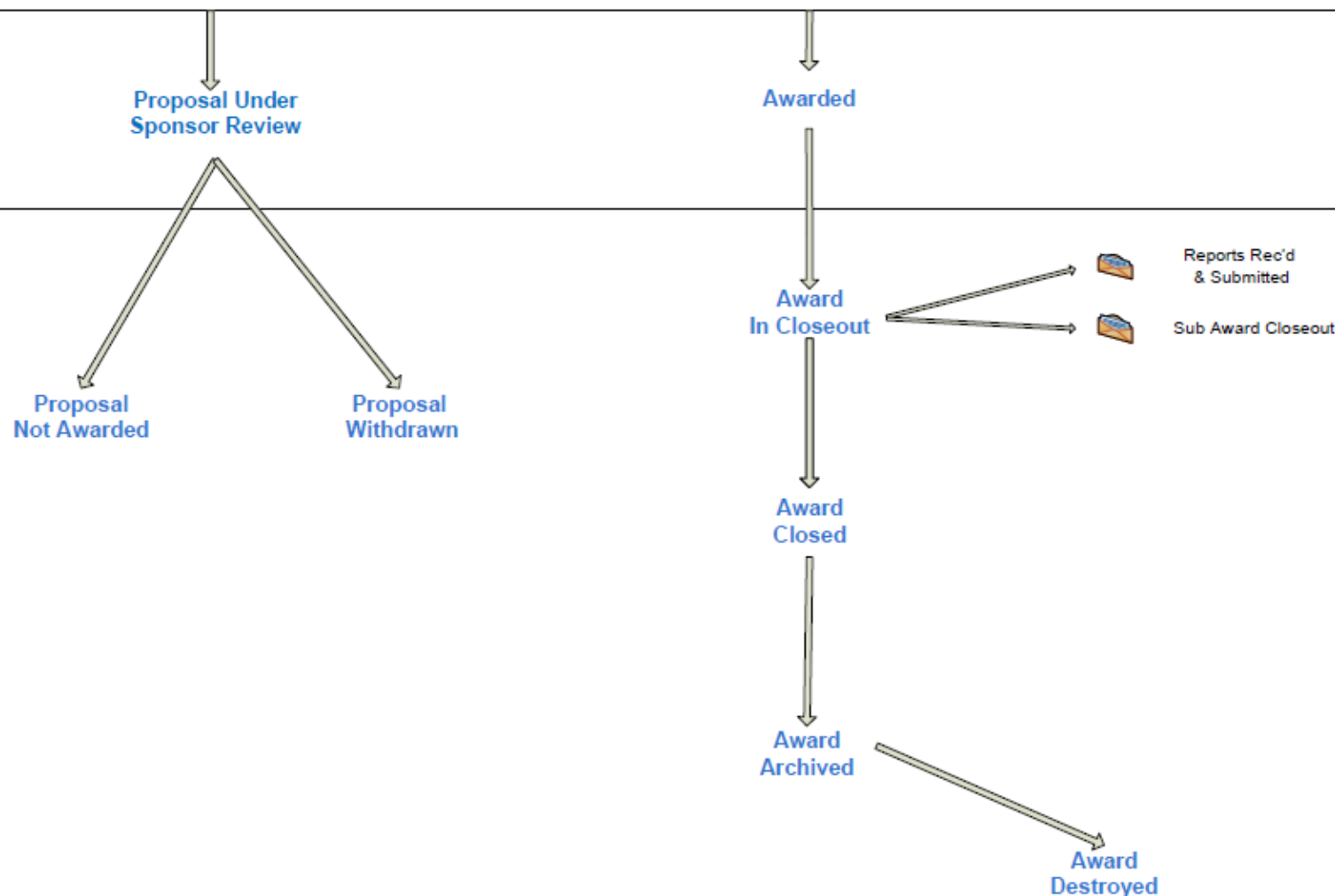
VCU OSP Sponsored Project Workflow Phases

<u>P0: Pre-Proposal</u>	<u>P1: Proposals</u>	<u>P2: Pre-Award</u>	<u>P3: Award</u>	A W A R D E D	<u>P4: Post Award</u>	<u>P5: Closeout</u>
<ul style="list-style-type: none"> CBH "Cart Before Horse" (Agreement with No IAF on file and not industry-sponsored clinical trial) Confidentiality Disclosure Agreements (CDA) Clinical Trial Pre Review 	<ul style="list-style-type: none"> New proposals Transfers In (PI new to VCU) New Master Agreement 	<ul style="list-style-type: none"> Just in time (JIT) Revised Budget Agreement 	<ul style="list-style-type: none"> Award Initial-Process VCUeRA 		<ul style="list-style-type: none"> Proposal Continuation/ Supplement Agreement Modification Task Order Progress Report Expanded Authority Request Prior Approval Request Subcontract Awarded Subsequent- Process VCUeRA 	<ul style="list-style-type: none"> Award in Closeout (Final Reports to Sponsor including: Technical, Financial, Property, Invention, and all Subawardees) Award Closed Award Archived Award Destroyed
CBH Implemented November 2009 CDA and CT Pre Review Implementation September 2011	Implemented August 2009	Implemented January 2010	Implemented May 2010		Implemented December 2010	Implementation September 2011

Office of Sponsored Programs Award Closeout

Current Status

Award Closeout



Closeout Reports

Phase 5: Closeout Workflow Statuses	
Award In Closeout	The period of performance for the award is completed and all required final reports are now due to the sponsor. OSP is in the process of assessing the need for and/or documenting submission of final reports to the sponsor.
Award Closed	All final reports have been submitted to the sponsor and the record is ready for physical and electronic closeout in OSP.
Award Archived	A complete electronic record of the entire file has been scanned and uploaded to the record and stored in OSP Shared Drive Archive Folder. No physical record of the project remains.
Award Destroyed	Period of required record retention has been met, permission to destroy record was obtained, and no physical or electronic copy of the project files remains.
Not Awarded and Withdrawn Workflow Statuses	
Proposal Not Awarded	The proposal was not awarded by the sponsor.
Proposal Withdrawn	VCU has withdrawn its proposal from consideration by the sponsor.

“Summer” Closeout Project

- Closeout needed for ~1200 records: Awards that have ended prior to 12/31/10
- In many cases, whatever was due to the sponsor has been submitted, i.e. we are not delinquent to the sponsor.
- When we mapped Closeout procedures, we created an “Award Destroyed” status that hadn’t previously existed. Before we could tackle what is in our “Award In Closeout” queue, we needed to assess and align our system statuses.
- Over the summer we have been updating “Award Closed” records to reflect either “Award Archived” or “Award Destroyed” status based on whether or not we have (1) met the 5 year record retention period and (2) retained an electronic image of entire record
- This has been a time-consuming but necessary effort

“Fall” Closeout Project

- Currently preparing our first batch of ~300 records to be sent out for imaging and, following our verification of the scanned image, paper records will be physically destroyed.
- We are also starting the daunting task of individually assessing our ~1200 “In Closeout” records.
- There are efficiencies that will help us with certain batches of records.
- But there are a lot of records to get through, with many unique sponsors. In these cases, we will need to assess our NOAs carefully and follow up by email with the PI (and FA if applicable.)
- OSP Post Award Team coordinates closeout for Government/NonProfit records: ospaward@vcu.edu

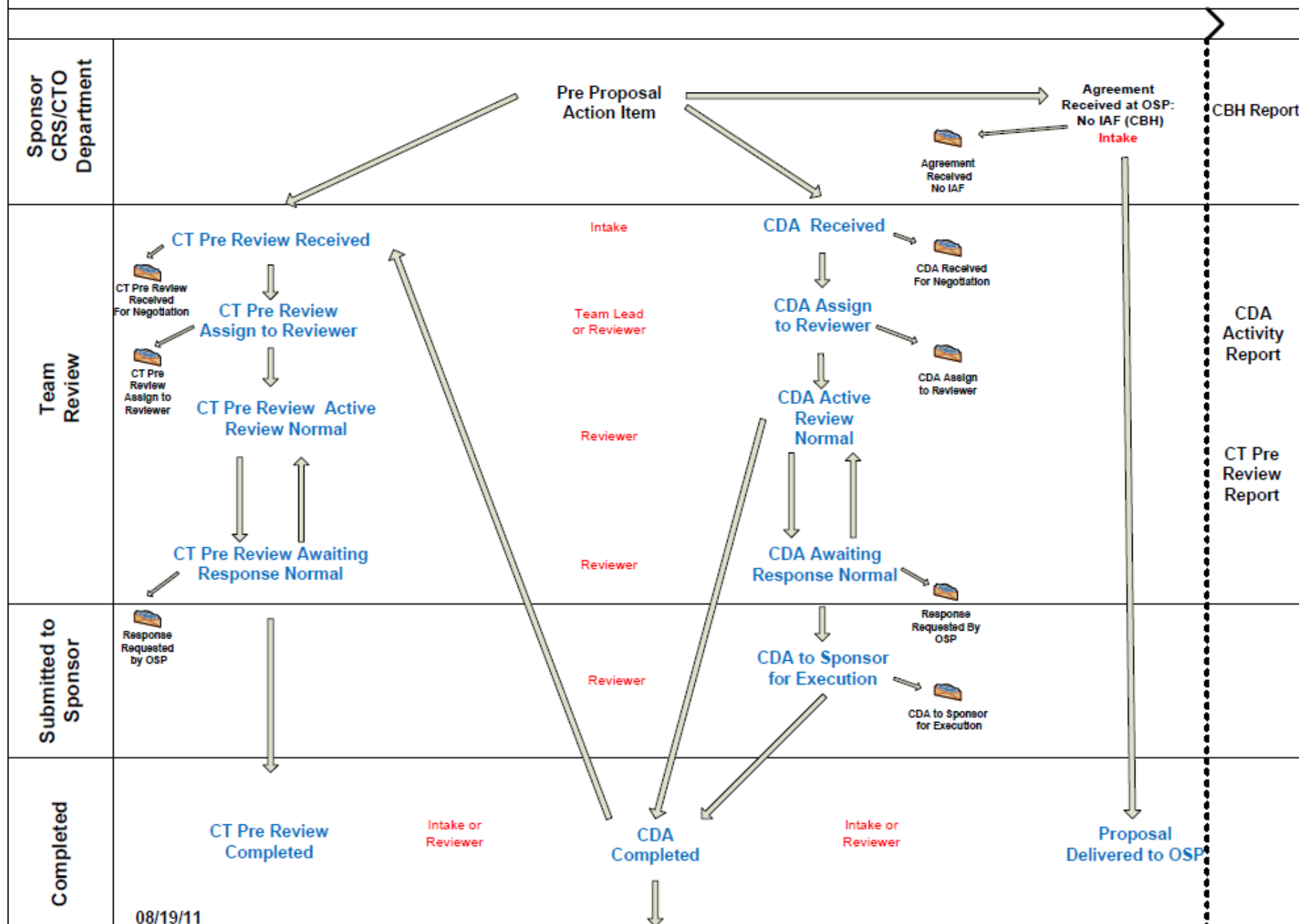
Amy Lutero, Post Award Manager

~~Summer~~ > Fall Closeout Project

Update on “Not Awarded” Records:

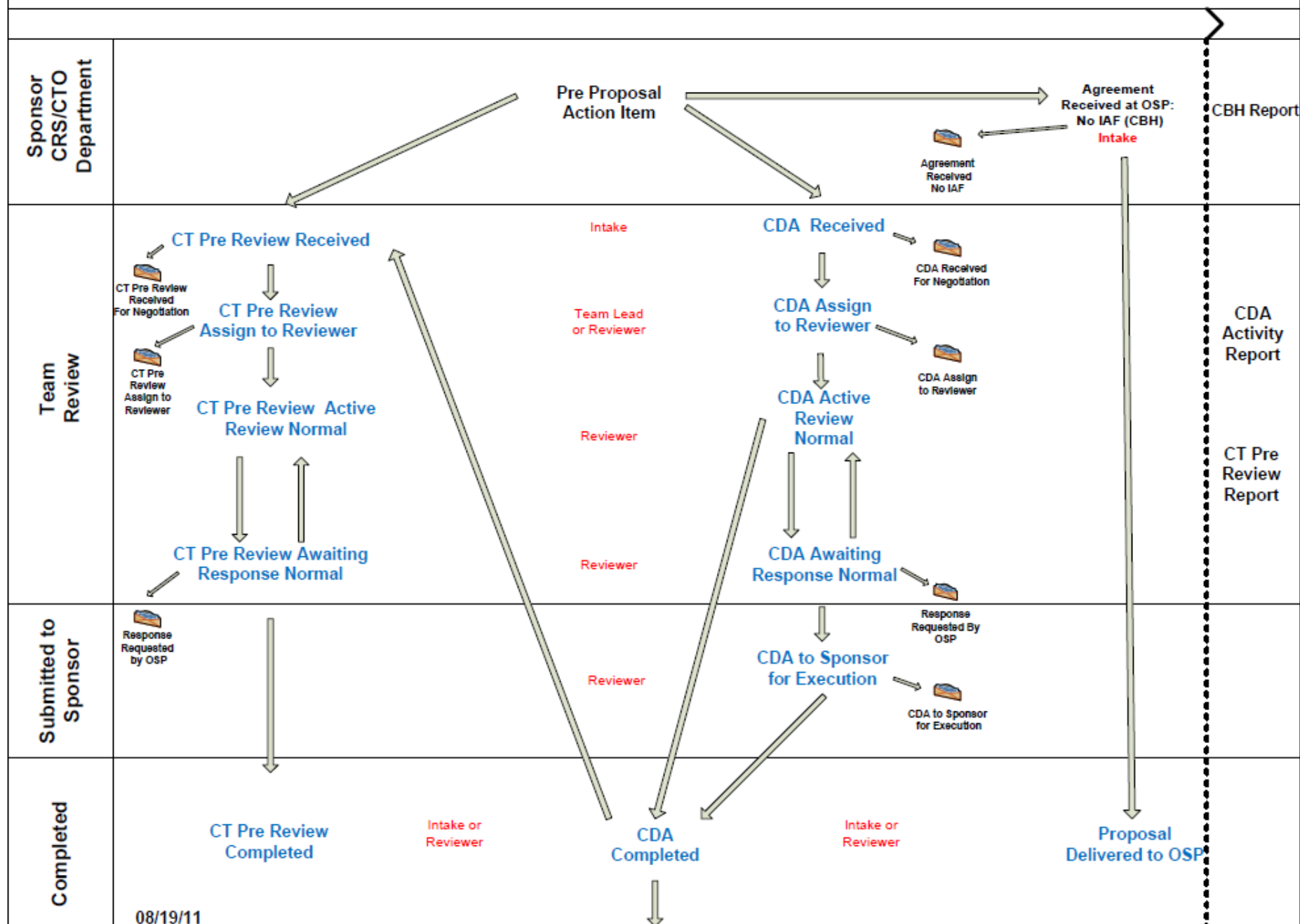
- Over spring and summer, we have updated hundreds of proposal records to reflect “Not Awarded” status.
- Our plan to initiate regular emails directly to Principal Investigators a year from submission to query status.
- This function will be handled by our Intake & Records Team. Automated emails to PI’s will be implemented with the hire of the Intake & Records Manager position.
- “Not Awarded” updates should be sent to dirospa@vcu.edu. Subject line should state “Not Awarded, PI last name, and PT or PD number.

Office of Sponsored Programs Pre Proposal Process



Current Statuses	Description of Status
Phase 0: Pre Proposal Workflow Statuses	
CDA Received	Confidentiality Disclosure Agreement received by OSP from PI.
CDA Assign to Reviewer	Confidentiality Disclosure Agreement assigned to reviewer for review and negotiation as appropriate.
CDA Active Review Normal	Confidentiality Disclosure Agreement is in the process of being reviewed. The CDA is being reviewed on the normal first-come, first-served basis.
CDA Awaiting Response Normal	The Confidentiality Disclosure Agreement has been reviewed. The reviewer has requested information from Sponsor, PI or Dept and is awaiting response.
CDA to Sponsor for Execution	OSP has signed the Confidentiality Disclosure Agreement and returned it to sponsor for countersignature. CDA cannot be processed and finalized until fully executed copy is received by OSP.
CDA Completed	CDA process has been completed. The CDA has been fully executed and distributed as appropriate.
CT Pre Review Received	Clinical Trial Pre Review received by OSP from PI.
CT Pre Review Assign to Reviewer	Clinical Trial Pre Review assigned to reviewer for review and negotiation as appropriate.
CT Pre Review Active Review Normal	Clinical Trial Pre Review is in the process of being reviewed on normal first-come, first-served basis.
CT Pre Review Awaiting Response Normal	The Clinical Trial Pre Review has been reviewed. The reviewer has requested information from Sponsor, PI or FA and is awaiting response.
CT Pre Review Completed	Clinical Trial Pre Review is Completed. Final Pre Review comments have been approved by OSP and either submitted directly to the sponsor or returned to the PI for transmission to the sponsor. Pre Review is a non-binding response and does not result in counter-signed binding agreement.

Office of Sponsored Programs Pre Proposal Process



Sponsored Project Administration Certificate Program

2011-2012 Program

No. of students initially enrolled: 55

No. of current students: 52

<u>Department</u>	<u>No. of Students</u>	<u>Department</u>	<u>No. of Students</u>
Dean's Office (Ahp)	1	Pediatrics	1
Epidemiology and Community Health	2	Physical Medicine and Rehabilitation	3
Family and Community Health Nursing	1	Qatar Campus	1
Genetics	2	Radiology	2
Humanities and Sciences	1	School of Medicine	2
Internal Medicine	7	School of Nursing	3
Management	1	School of the Arts	1
Massey Cancer Center	2	Social and Behavioral Health	1
MSW Program	2	SOE Ed Ldshp Dept	2
Obstetrics/Gynecology	1	SOE Spec Ed and DP RRTC	2
Office of Research	8	Student	1
Parkinsons Center of Excellence	1	Surgery	2
Pathology	1	Wilder School	1
~ 26 Departments represented		Total	52

Sponsored Project Administration Certificate Program

<u>Certification Program Live Dates (2011-2012)</u>			
First Live Session Mod 1 (Held at Student Commons)	September 7	10-2pm	Wed
Live Session Mod 2	September 28	10-2pm	Wed
Live Session Mod 3	October 19	10-2pm	Wed
Live Session Mod 4	November 16	10-2pm	Wed
Live Session Mod 5	December 14	10-2pm	Wed
Certificate Presentation Jan. 2012 (During RACM)	January 26	1-3pm	Thurs
Note: All live sessions (except for Sept. 7 session) to be held at Larrick Student Center			



Research Administrators and Compliance Meeting 9/21/2011

Update From G&C

Accounting/Effort Reporting

Welcome Syreeta Thomas

- Welcome to Syreeta Thomas
- Grant Accountant-Joined Delta Team on July 25, 2011
- Prior employment as Grant Accountant with the VA Department of Health, as well as with federal contractors.
- Contact 828-4575 or sthomas33@vcu.edu

Effort Reporting – Top 10 Things a P.I. Should Know.....

- Salaries charged to sponsored projects are reasonable in relation to the work performed.
- Faculty and staff have met their commitments to sponsored projects.

Success in the effort realm depends on careful attention to important issues throughout the sponsored projects lifecycle and communications with the P.I.

Approaching Dates

- Effort Reporting Instructor- Led Course
10-06-2011 Sanger Hall B1-20
- ECRT Period 06-10-11 to 09-09-11 is
scheduled to be released on 10-15-
11(Quarterly Certifiers)
- ECRT Period 12-10-10 to 06-09-11 ends on
10-21-11(Semiannual Certifiers)

Stimulus Reporting (ARRA)

- Your assistance by responding to monthly requests for supporting documentation for JVs related to stimulus awards in a timely manner is appreciated. Delays result in VCU being delinquent with the Federal Reporting deadline.

Status of Backlogged Close-outs

- 2 Populations:

- 1 - Grants Ended Dec 31, 2008 & Prior

- 2 - Grants Ended Jan 1, 2009 to Oct 31, 2010

As of 2-2-11 #1 was 370 and #2 was 720

As of 9-14-11 #1 was zero and #2 was 8

There is still work to be done to properly and timely close-out projects. Your assistance is appreciated!

Reminders.....

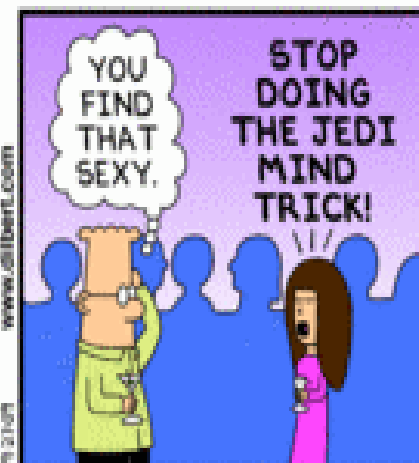
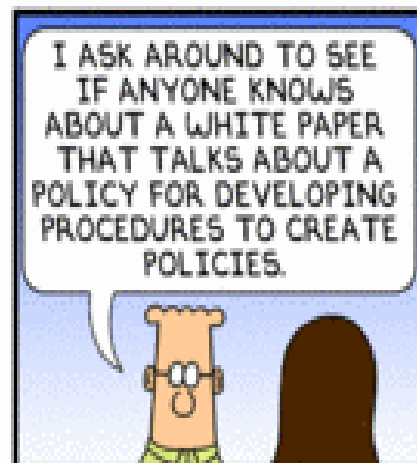
- Cost transfers to sponsored program indexes may be made only within 60 days from the date of the month end Banner report on which the charge first appears.
- Once an index closes and the final financial report has been submitted to the sponsor, no expenses may be charged to the closed index but must be funded elsewhere.

Reminders continued.....

- Please use the available Banner reports, ePrint reports, and VCU Reporting Center reports to reconcile your grants monthly
- Non-compliant labor PHARED transactions identified recently: May-71 transactions; June-87 transactions; July-23 transactions

Current and Future Initiatives

- Changing Industry Clinical Trial budgets in Banner to reflect payments received
- Addressing special reporting needs (e.g. Financial Aid grant drawdown monitoring, clinical effort total compensation, and electronic FER)
- Working with Controller to address process changes needed for Dashboard project



Initiatives continued.....

- G&C staff are participating on Finance and Administration Teams to further improve processes, communications, outreach, people development, and best practices
- Assess the potential need to upgrade to newer versions of ECRT
- Engage the VCU Survey Research Lab to develop and administer a survey to determine what is important to you.

Thank You

- Thanks for your continued support and your efforts to minimize compliance risks in fiscal administration
- Please don't hesitate to contact your responsible grant accountant, or Effort Reporting if you need assistance or have questions.