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

Virginia Commonwealth University
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
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

- 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

Disclosure of SFI
Compliance with Institutional Policy

Investigator

Institutional Policy Implementation
Evaluation of SFI
Identification of FCOI
Management

Compliance with Regulations Reporting to NIH

Institution

Oversight

NIH

PHS regulation 42 CFR Part 50, Subpart F and 45 CFR Part 94
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

• 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
    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

<table>
<thead>
<tr>
<th>P0: Pre-Proposal</th>
<th>P1: Proposals</th>
<th>P2: Pre-Award</th>
<th>P3: Award</th>
<th>P4: Post Award</th>
<th>P5: Closeout</th>
</tr>
</thead>
<tbody>
<tr>
<td>• CBH “Cart Before Horse” (Agreement with No IAF on file and not industry-sponsored clinical trial)</td>
<td>• New proposals</td>
<td>• Just in time (JIT)</td>
<td>• Award Initial-Process VCUeRA</td>
<td>• Proposal Continuation/Supplement</td>
<td>• Award in Closeout (Final Reports to Sponsor including: Technical, Financial, Property, Invention, and all Subawardees)</td>
</tr>
<tr>
<td>• Confidentiality Disclosure Agreements (CDA)</td>
<td>• Transfers In (PI new to VCU)</td>
<td>• Revised Budget</td>
<td>• Agreement</td>
<td>• Agreement Modification</td>
<td>• Award Closed</td>
</tr>
<tr>
<td>• Clinical Trial Pre Review</td>
<td>• New Master Agreement</td>
<td></td>
<td></td>
<td>• Task Order</td>
<td>• Award Archived</td>
</tr>
<tr>
<td><strong>CBH Implemented November 2009</strong></td>
<td><strong>Implemented August 2009</strong></td>
<td><strong>Implemented January 2010</strong></td>
<td><strong>Implemented May 2010</strong></td>
<td><strong>Implemented December 2010</strong></td>
<td><strong>Implementation September 2011</strong></td>
</tr>
</tbody>
</table>

VCU OSP Sponsored Project Workflow Phases ©- 08-23-11
Office of Sponsored Programs Award Closeout

Current Status

- Proposal Under Sponsor Review
  - Proposal Not Awarded
  - Proposal Withdrawn
- Awarded
  - Award In Closeout
    - Reports Read & Submitted
    - Sub Award Closeout
  - Award Closed
    - Award Archived
  - Award Destroyed

Award Closeout

04/12/11
### Phase 5: Closeout Workflow Statuses

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Award In Closeout</td>
<td>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.</td>
</tr>
<tr>
<td>Award Closed</td>
<td>All final reports have been submitted to the sponsor and the record is ready for physical and electronic closeout in OSP.</td>
</tr>
<tr>
<td>Award Archived</td>
<td>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.</td>
</tr>
<tr>
<td>Award Destroyed</td>
<td>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.</td>
</tr>
</tbody>
</table>

### Not Awarded and Withdrawn Workflow Statuses

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal Not Awarded</td>
<td>The proposal was not awarded by the sponsor.</td>
</tr>
<tr>
<td>Proposal Withdrawn</td>
<td>VCU has withdrawn its proposal from consideration by the sponsor.</td>
</tr>
</tbody>
</table>
“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.
<table>
<thead>
<tr>
<th>Current Statuses</th>
<th>Description of Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 0: Pre Proposal Workflow Statuses</strong></td>
<td></td>
</tr>
<tr>
<td>CDA Received</td>
<td>Confidentiality Disclosure Agreement received by OSP from PI.</td>
</tr>
<tr>
<td>CDA Assign to Reviewer</td>
<td>Confidentiality Disclosure Agreement assigned to reviewer for review and negotiation as appropriate.</td>
</tr>
<tr>
<td>CDA Active Review Normal</td>
<td>Confidentiality Disclosure Agreement is in the process of being reviewed. The CDA is being reviewed on the normal first-come, first-served basis.</td>
</tr>
<tr>
<td>CDA Awaiting Response Normal</td>
<td>The Confidentiality Disclosure Agreement has been reviewed. The reviewer has requested information from Sponsor, PI or Dept and is awaiting response.</td>
</tr>
<tr>
<td>CDA to Sponsor for Execution</td>
<td>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.</td>
</tr>
<tr>
<td>CDA Completed</td>
<td>CDA process has been completed. The CDA has been fully executed and distributed as appropriate.</td>
</tr>
<tr>
<td>CT Pre Review Received</td>
<td>Clinical Trial Pre Review received by OSP from PI.</td>
</tr>
<tr>
<td>CT Pre Review Assign to Reviewer</td>
<td>Clinical Trial Pre Review assigned to reviewer for review and negotiation as appropriate.</td>
</tr>
<tr>
<td>CT Pre Review Active Review Normal</td>
<td>Clinical Trial Pre Review is in the process of being reviewed on normal first-come, first-served basis.</td>
</tr>
<tr>
<td>CT Pre Review Awaiting Response Normal</td>
<td>The Clinical Trial Pre Review has been reviewed. The reviewer has requested information from Sponsor, PI or FA and is awaiting response.</td>
</tr>
<tr>
<td>CT Pre Review Completed</td>
<td>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.</td>
</tr>
</tbody>
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## Sponsored Project Administration Certificate Program

### 2011-2012 Program

- No. of students initially enrolled: 55
- No. of current students: 52

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

~ 26 Departments represented

| Total | 52  |

- ~ 26 Departments represented
# Sponsored Project Administration Certificate Program

<table>
<thead>
<tr>
<th>Certification Program Live Dates (2011-2012)</th>
</tr>
</thead>
</table>
| 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 |
(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 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
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!
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.
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
Dilbert, I want you to develop a procedure for creating policies.

Do we have a policy on how to develop procedures?

I think someone wrote a white paper on that.

What's the procedure for finding white papers?

Maybe you could ask around.

Later that night

So, what do you do?

I ask around to see if anyone knows about a white paper that talks about a policy for developing procedures to create policies.

Stop doing the Jedi mind trick!
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.
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.