

**Research Administration and Compliance Meeting**  
**Wednesday, May 23, 2012**  
**1:00 – 3:00 p.m.**  
**Larrick Hall, Court End B**

**Agenda**

Welcome

General Items/Updates

- Financial Conflict of Interest Update – Monika Markowitz
- CCTR Service Center Information – David Allen
- Mandatory Training Status – Sue Robb
- Research Performance Progress Reports (RPPR) – Sue Robb
- NIH Special Council Review – Sue Robb
- G&C and OSP Office Relocations – Sue Robb/Mark Roberts

OSP Updates

- Staffing Updates – Annie Publow
- Faculty Retirement/PI Termination – Annie Publow
- Jeffress Memorial Trust – Annie Publow
- Hospital Employees Conducting Research – Melanie Wiggins

G&C/Effort Reporting Updates – Mark Roberts

- Staffing Updates
- ECRT Upgrade

Future RACM Dates, 1-3 p.m.

- October 3, 2012 (note Change)!!
- January 23, 2013
- May 22, 2013

# Interested in Conflict of Interest?

## New VCU Policy and Processes

Monika S. Markowitz, PhD

Director, Office of Research Integrity and Ethics

Chair, Conflict of Interests Committee

RACM

May 23, 2012

# Pending revision of VCU Research COI policy

& planned implementation of new financial  
interest reporting process

**WHY?** Revised Federal regulation: *Responsibility of  
Applicants for Promoting Objectivity in Research for which  
Public Health Service Funding is Sought . . .*

Published 8/25/2011,  
compliance by 8/24/2012

# [DRAFT] Research Conflict of Interests Policy

## Conflict of Interest (COI)

Conflicts of Interest exist when financial or other personal interests (as termed in the Virginia Code) or considerations of the Investigator, or members of his or her immediate family, **may directly and significantly affect, or have the appearance of directly and significantly affecting, an Investigator's professional judgment in exercising any University duty or responsibility, including the design, conduct or reporting of research.** Financial Conflicts of Interest in research occur when the Investigator, or any member of that person's immediate family (spouse, or domestic partner, and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent), possesses a Significant Financial Interest (SFI) in a research activity that is in conflict with his or her University responsibilities.

# *FCOI Regulations - Final Rule*

- Revised regulations : *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought ...*
- Federal Register published August 25, 2011
  - [http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)
- 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
- If implement Rule prior to August 24, 2012, must compliance with it

# Major Changes in the Regulations

- De minimus threshold for significant financial interest (SFI) decreased to \$5,000.
- 'Investigator' training – at least every 4 years
- 'Investigator' reports compensated travel
- 'Investigator' reports FI based on institutional responsibilities
- Institution has onus of determining whether SFI constitutes FCOI (Financial COI)
- Public disclosure – website or within 5 days
- Increased reporting to NIH re: FCOI and management



# Institutional Responsibilities

- Institutions must establish standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.  
>>> Management of FCOI by COIC
- Maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Web site.

# Institutional Responsibilities:

## Investigator Disclosure of SFIs

### Reporting of Financial Interests (FIs)

- **At time of Application:** Require that each Investigator, including subrecipient Investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application.
- **Annually:** Require each Investigator, including subrecipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award.
- **Within 30 days:** Require each Investigator, including subrecipient Investigator, if applicable, who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.



# **Institutional Responsibilities:**

## **Subrecipient Requirements**

- Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements.
- Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations.

# **Institutional Responsibilities:**

## **Enforcement**

- Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance.

# How will VCU be implementing the Final Rule?

- 'Investigators' report requested Financial Interests regardless of funding source
- Financial Interests reported in Click Commerce electronic platform – annually and updates in 30 days
- 'Forced' COI Training precedes required annual financial interests report
- Research relatedness reported within the Financial Interests Report (FIR)
- Travel reporting within FIR – sponsored and reimbursed
- Public disclosure concerning managed FCOI for senior/key personnel within 5 days

# Definitions from VCU DRAFT Policy

## Investigator

Investigator describes any individual, regardless of title, role or position, who is **responsible for the design, conduct, or reporting of research**. Individuals with such research responsibilities may be, but are not limited to, senior/key personnel, sub/co-investigator or subrecipient investigator, medical investigator, collaborator, consultant, student, trainee, or research coordinator. **Exceptions include students or other personnel whose research activities are directly supervised**. By considering an individual's degree of independence relative to the research, **the Principal Investigator on the proposal or protocol designates the individuals who meet the definition of 'Investigator.'**

## Investigator's Institutional (or University) Responsibilities

Such responsibilities describe those **professional responsibilities an investigator has by virtue of being a VCU employee, student, or trainee**. These may include for example: teaching, professional practice, service on committees, research and research consultation.

Report Financial Interests held by Investigator or any member of his or her immediate family (spouse, or domestic partner, and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent)

- All Financial Interests, including compensated travel (for Investigator only), on an annual basis in a secure database.
- Updates within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) 1) a new Financial Interest in an entity not previously reported AND/OR 2) an additional remunerated Financial Interest, that, when added to a Financial Interest in a previously reported entity, meets or exceeds \$5,000 IF research is related, or could appear to be related, to the Financial Interest.
- Research-related questions concerning Financial Interests specifically associated with proposed and on-going research on an annual basis .
- Update research relatedness of financial interests, including compensated travel, for every Sponsored Program submission, IRB or IACUC submission, as applicable.



# Financial Interests to be reported include anything of monetary value:

- **salary or other payments for services** (e.g., consulting fees, honoraria, or payments for serving on a corporate Board of Directors, Scientific Advisory Board, or holding a position in a company);
- **income from seminars, lectures, service or teaching engagements sponsored by for-profit entities, federal, state, or local agencies or public or non-profit entities;**
- **equity interests** (e.g., stocks, stock options, or other ownership interests);
- **intellectual property rights** (e.g., patents, copyrights, and royalties from such rights,); and
- **travel by the Investigator that is reimbursed or paid by a third party** (i.e., travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to an Investigator's Institutional Responsibilities.

Financial Interest does not include salary or reimbursement originating from VCU.

# Determinations by COI Committee

By expedited review, or in convened committee:

- 1) no financial Conflict of Interests exists,
- 2) a financial Conflict of Interests exists, or
- 3) a Competing Financial Interest exists for human subjects research.

# Implementation “Plan”

- **Likely** phase in with all ‘investigators’ associated with PHS-funded (NIH) research that will be active on 8/24/2012
- ‘Investigators’ will be required to complete the Financial Interest Report (FIR) to be in compliance no later than 8/24/2012
- Triggered Financial Interests will be reviewed for SFI and evaluated for FCOIs
- Phase in for subsequent proposal and protocol submissions

# Additional required VCU responsibilities as per the PHS “Objectivity in Research” regulations:

- **Subrecipients:** VCU is required to verify with subrecipient institutions whether this Policy in its entirety or whether the financial Conflict of Interest policy of the subrecipient institution will apply to its investigators who are collaborating with VCU investigators.
- **Training requirement:** Each Investigator must complete training prior to beginning research and at least every 4 years; also required if the Policy changes substantially, if an investigator is new to VCU, and if an investigator is found to be non-compliant.
- **Publicly available information about FCOIs:** As per regulation, VCU will make available required information about current financial COIs held by Senior/Key Personnel on PHS funded research to any requestor within 5 business days of a request.

## Additional required VCU responsibilities as per the PHS “Objectivity in Research” regulations:

- **Failure to report or review SFI in a timely manner:** If such failure is identified by VCU, the SFI must be reviewed for financial COI and an interim management plan implemented within 60 days.
- **Retrospective review for bias and mitigation report for noncompliance:** Upon a determination of non-compliance with this policy, VCU is required, as per regulation, to complete a retrospective review of the research project as well as the Investigator’s activities within 120 days to determine if there was bias in the design, conduct, or reporting of the research. A COI mitigation report must be sent to the PHS agency if bias is found. The agency may determine that further corrective action is needed.



# Summary of FCOI Noncompliance

## FCOI REPORT (within 60 days)

- Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.

## RETROSPECTIVE REVIEW (to determine bias)

- If an FCOI exists, complete and document a retrospective review within 120 days of the Institution's determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.

## UPDATE/REVISE FCOI REPORT (following retrospective review)

- If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward.

## REPORT (promptly after retrospective review)

- If bias is found, notify NIH promptly
- Submit a Mitigation Report through FCOI Module

## ANNUAL FCOI

- Submit annual FCOI report thereafter

# CCTR Service Center

# CCTR

- 6 main areas of fee for services
  1. Budget, Planning, and Regulatory Submissions
  2. Study Coordination
  3. CRS Lab
  4. Unit
  5. Bio nutrition
  6. Biomedical Informatics

# Budget, Planning, and Regulatory Submissions

- Budget development and negotiation for clinical trials
- Fiscal compliance planning
- Medicare cost-coverage analysis
- IRB submissions

# Study Coordination

- Pool of trained clinical research practitioner coordinators to provide
  - Regulatory documentation and study start-up
  - Participant recruitment
  - Data collection
  - Case report forms and monitoring of visits



## CRS Lab

- Research based laboratory able to perform a wide variety of testing and services based on staff expertise
  - Insulin and Glucose testing
  - Specimen processing including glucose analyzation, spectrophotometry, luminex multiple array, spectrofluorometry, along with others

# Unit

- Full service hospital unit locating in North Hospital of the 8<sup>th</sup> floor
- 11 beds for overnight stays, exam room, room for specialized testing, and interviews
- Full service research trained nursing staff with 24 hour staffing

# Bio Nutrition

- Registered dietitian that can formulate and prepare
  - Experimental diets
  - Dietary analysis
  - Anthropometric measurements
  - Patient consultations
  - Full metabolic kitchen

# Biomedical Informatics

- Perform and complete technical projects related to REDCap
  - Creation of complicated databases and surveys
  - Migration of databases into REDCap
  - Other specialized services

# CCTR Service Center Information

- Will be posted to CCTR Website CCTR.vcu.edu
- Should be listed as CCTR Services
- Document will include all rates and explanation of services
- For all services within the CRS please complete the CRS Intake Survey under “Clinical Research Services” on the Website or the BIC Support Request form for biomedical informatics help on the Website.



Update May 2012

# **MANDATORY INVESTIGATOR AND ADMINISTRATOR TRAINING**

# Required Training for PIs and Administrators

Course Number	Course Description	Registered
TRAIN-2012-001-2012Spring	Allied health	70
TRAIN-2012-002-2012Spring	Arts	30
TRAIN-2012-003-2012Spring	Business	34
TRAIN-2012-004-2012Spring	Community Engagement	14
TRAIN-2012-005-2012Spring	Dentistry	31
TRAIN-2012-006-2012Spring	Education	215
TRAIN-2012-007-2012Spring	Engineering	71
TRAIN-2012-008-2012Spring	Hummanities and Sci	254
TRAIN-2012-009-2012Spring	Life Sciences	26
TRAIN-2012-010-2012Spring	Massey	67
TRAIN-2012-011-2012Spring	Nursing	25
TRAIN-2012-012-2012Spring	Pharmacy	114
TRAIN-2012-013-2012Spring	Social Work	20
TRAIN-2012-014-2012Spring	VP Research	214
TRAIN-2012-015-2012Spring	Medicine	1354
TRAIN-2012-016-2012Spring	VP Health Sciences	33
TRAIN-2012-017-2012Spring	Controller and G&C	42
TRAIN-2012-018-2012Spring	Provost	13
<b>Total Enrolled (Blackboard)</b>		<b>2627</b> **Number as identified in initial lists
<b>Completed (InfoEd)</b>		
	Admin	143
	Investigator	519
<b>Total Completed</b>		<b>662</b>
<b>Percent Complete</b>		<b>25%</b>

# About the training/course

- A. Course must be complete by May 31, 2012
- B. You need to complete the course if:
  - 1. You are a PI on a sponsored project
  - 2. You are Co-investigator, investigator, faculty on a sponsored project
  - 3. You are lab technician, researcher, coordinator, etc. on a sponsored project
- C. You do not need to take the course if:
  - 1. You are a work study student
  - 2. You have clerical or administrative functions and are not on a sponsored project
- D. If you are not sure if you need to take the course(s) please email Jose Alcaine at [jgalcaine@vcu.edu](mailto:jgalcaine@vcu.edu) or call at 828-2508
- E. If role in project is research related or research focused, complete the “Investigator” content (2 exams). If role is more administrative or fiscal in nature, involving procurement, etc., complete the “Administrator” content (3 exams).

Research Administration and Compliance Meeting  
May 2012

# RESEARCH PERFORMANCE PROGRESS REPORT

# What is a RPPR?

- Uniform Progress Report Format used by all federal agencies that support research and research-related activities
- Established by OMB/OSTP Policy dated 4/21/2010
- Agency- or Program-Specific requirements will require additional OMB review and clearance



# Agency Implementation

- DHHS – January 2013
- DHS – September 2012
- DOC – October 2013
- DoD – January 2014
- DOE – November 2010
- DoED – June 2011
- DOJ – September 2011
- EPA – January 2012
- NASA – January 2014
- NEH – September 2012
- NSF – January 2013
- USDA – September 2013/2014

# Cover Page Data Elements

- Federal Agency and Organization Element to Which Report is Submitted
- Federal Grant or Other Identifying Number Assigned by Agency
- Project Title
- PD/PI Name, Title and Contact Information (e-mail address and phone number)
- Name of Submitting Official, Title, and Contact Information (e-mail address and phone number), if other than PD/PI
- Submission Date
- DUNS and EIN Numbers
- Recipient Organization (Name and Address)
- Recipient Identifying Number or Account Number, if any
- Project/Grant Period (Start Date, End Date)
- Reporting Period End Date
- Report Term or Frequency (annual, semi-annual, quarterly, other)
- Signature of Submitting Official (signature shall be submitted in accordance with agency specific instructions)

# Accomplishments

- ⦿ What are the major goals and objectives of the project?
- ⦿ What was accomplished under these goals?
- ⦿ What opportunities for training and professional development has the project provided?
- ⦿ How have the results been disseminated to communities of interest?
- ⦿ What do you plan to do during the next reporting period to accomplish the goals and objectives?

# Products

- ⦿ Publications, conference papers, and presentations;
- ⦿ Website(s) or other Internet site(s);
- ⦿ Technologies or techniques;
- ⦿ Inventions, patent applications, and/or licenses;
- ⦿ Other products, such as data or databases, physical collections, audio or video products,  
software or NetWare, models, educational aids or curricula, instruments, or equipment

# Participants & Other Collaborating Organizations

- ⦿ What individuals have worked on the project?
- ⦿ What other organizations have been involved as partners?
- ⦿ Have other collaborators or contacts been involved?



# Impact

- ◎ What is the impact on
  - the development of the principal discipline(s) of the project;
  - other disciplines;
  - the development of human resources;
  - physical, institutional, and information resources that form infrastructure;
  - technology transfer (include transfer of results to entities in government or industry,
  - adoption of new practices, or instances where research has led to the initiation of a startup company); or
  - society beyond science and technology.

# Changes/Problems

- ◎ Provide the following additional information, if applicable:
  - Changes in approach and reasons for change.
  - Actual or anticipated problems or delays and actions or plans to resolve them.
  - Changes that have a significant impact on expenditures.
  - Significant changes in use or care of animals, human subjects, and/or biohazards.

# Special Reporting Requirements

- ⦿ Agency Specific
- ⦿ Budgetary Information
  - SF 424 R&R, if agency requires (NIH has already indicated that it will not be required for SNAP awards)

# Submissions

- NSF – Research.gov
- NIH – eRA Commons
- DoE – FedConnect
- DoD – “Initial electronic implementations of RPPR-compliant reporting requirements will be determined on a Component-level basis until a DoD-wide electronic system can be established.”
- DHS – Adobe and e-mail

For PIs with More Than \$1.5M Total Annual Support

# NIH SPECIAL COUNCIL REVIEW



# NIH Pilot Program

- SCR Procedures – May IC Council meetings
  - Council members asked to provide additional consideration of applications from well-supported investigators who currently receive more than \$1.5M in Research Project Grants.

VCU  
Office of Sponsored Programs  
Office of Research



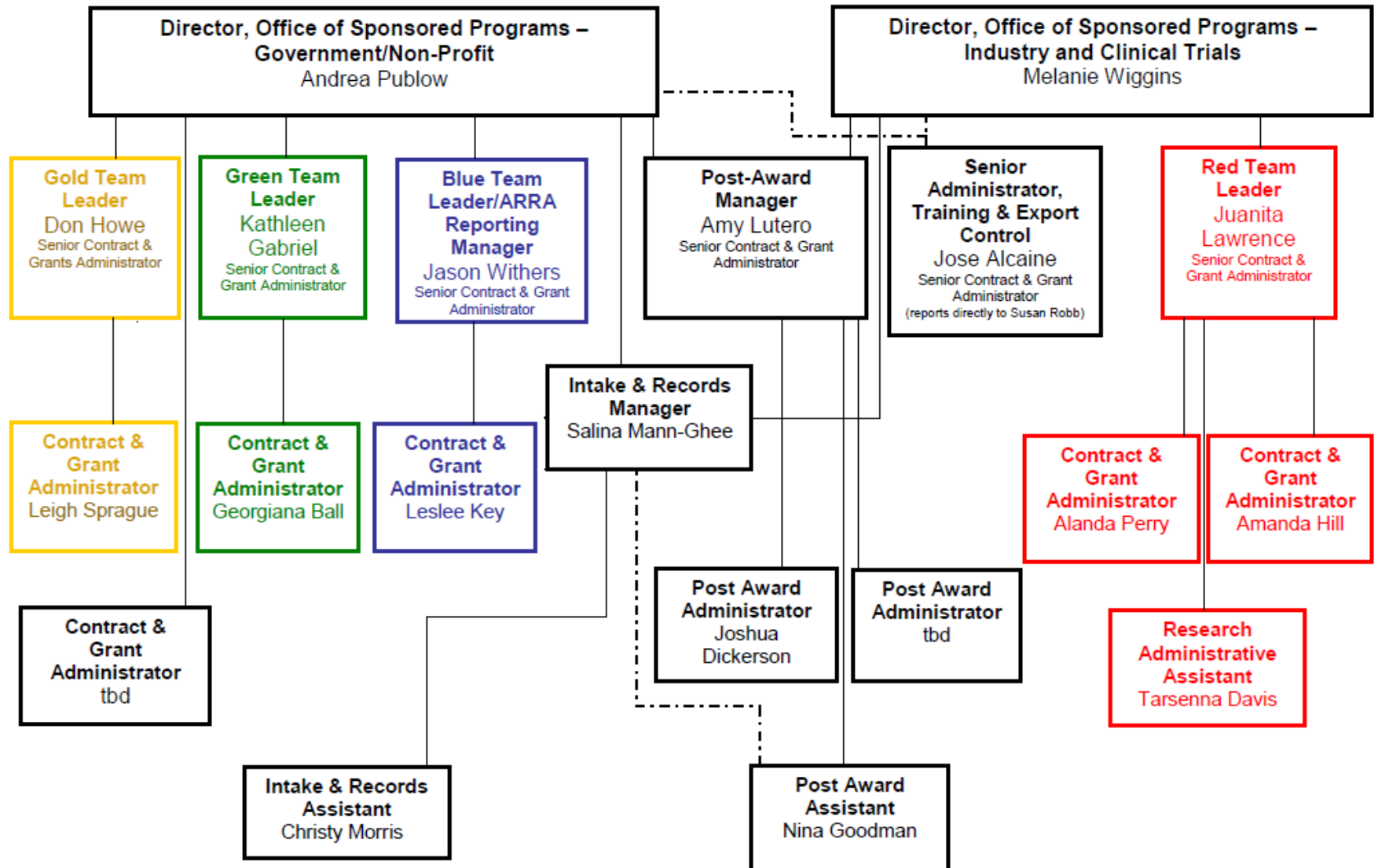
Committee on the Administration of Research's  
**Research Administration and Compliance Meeting**  
OSP Update  
Annie Publow, Director of Sponsored Programs,  
Government/NonProfit Support  
May 23, 2012

# OSP Update

## Presentation Topics:

- OSP Staffing Update
- Closeout of “Not Awarded” Proposals
- PI Termination/Faculty Retirement
- Jeffress Memorial Trust
- Sponsored Project Administration Certification Program
- VCU Surplus

## VCU OFFICE OF SPONSORED PROGRAMS



April 2012

# Closeout of “Not Awarded” Proposals

OSP Focus on Clean up:

Physical and Electronic Records

- 1082 records since start of calendar year
- Initiated a monthly email in February sent directly to investigators for projects with proposed start date of 12 months ago or longer

We appreciate the timely and strong response!



# PI Termination

Contact OSP when you know faculty are leaving:

- Assess active sponsored projects
- Projects typically...
  - Transfer with PI to new institution (Prior Approval Request)
  - Remain at VCU under different PI leadership (Prior Approval Request)
  - Close out (OSP needs final technical and invention reports)
- Much easier to work through process before the PI leaves
  - Close out becomes responsibility of current Department Chair if PI has gone
- Coordinate within OSP: We can generate a PI Status Report
  - Active Government/NonProfit Projects >Green, Blue, Gold Teams
  - Active Industry Projects>Red Team
  - Projects with “in Closeout” status>Post Award Team

# PI Status Report

Report Manager - Windows Internet Explorer

https://vcu.sra-review.research.vcu.edu/Reports/Pages/Report.aspx?ItemPath=%2FOSP+Reports%2FOSP+PI+Status+Report

File Edit View Favorites Tools Help

Convert Select

WEB SEARCH My Apps

Report Manager

Home > OSP Reports > **OSP PI Status Report**

Home | My Subscriptions | Help

Search for:  Go

View Properties History

Please select PI:  Sort by:

Select Principal Investigator  
Abalg, Justine  
Abbate, Antonio  
Abd-Elfattah, Anwar  
Abdrakhmanova, Galia  
Abell, Melissa  
Aberg, Karolina  
Abouranos, Michel  
Abraham, Donald  
Abrams, Lisa  
Accardo, Pasquale  
Accordino, John  
Acosta, Mario  
Acovedo, Edmund  
Adams, Stephanie  
Addesa, Anthony  
Adelaar, Robert  
Adkins, Daniel  
Adler, Robert  
Adler, Steven  
Adler, Stuart  
Adney, Scott  
Aggarwal, Arpita  
Agris, Jacob  
Aiken, Peter  
Aisiku, Imoigbele  
Albarali, Hamid  
Albani, Homayoon  
Al-Horani, Rami

Internet 100%

# PI Status Report

OSP PI Status Report									
Institution #	PI	Department	Sponsor	Title	Award Start date	Award End date	Team	Status	
PT091022	Mitzi Nagarkatti	Massey Cancer Center	National Institute of Allergy and Infectious Diseases/NIH/DHHS	Cytotoxic Lymphocytes in Acute Lung Injury	03/15/2004	08/01/2005	BLUE	Award Archived	
PT091023	Mitzi Nagarkatti	Microbiology and Immunology	National Heart, Lung, and Blood Institute/NIH/DHHS	Endothelial Cell Injury by Cytolytic Lymphocytes	04/01/1998	04/30/2007		Award Archived	
PT091025	Mitzi Nagarkatti	Microbiology and Immunology	National Institute of Allergy and Infectious Diseases/NIH/DHHS	Role of CD44 in EC Injury and Melanoma Therapy	12/01/2002	08/14/2005	BLUE	Award Archived	
PT091026	Mitzi Nagarkatti	Microbiology and Immunology	National Heart, Lung, and Blood Institute/NIH/DHHS	Role of CD44 Isoforms in Endothelial Cell Damage	08/01/2000	07/31/2003		Award Destroyed	
PT091024	Mitzi Nagarkatti	Microbiology and Immunology	National Institute of Environmental Health Sciences/NIH/DHHS	Role of Apoptosis in TCDD-Induced Immunotoxicity	09/25/2002	09/24/2004		Award Destroyed	
PT090026	Mitzi Nagarkatti	Massey Cancer Center	American Cancer Society, Inc.	American Cancer Society Institutional Grant	07/01/2000	06/30/2003		Award Destroyed	
PT091021	Mitzi Nagarkatti	Microbiology and Immunology	National Institute on Drug Abuse/NIH/DHHS	Cannabinoid-Induced Apoptosis of Immune Cells	09/26/2001	08/31/2004		Award Destroyed	
PT096156	Mitzi Nagarkatti	Microbiology and Immunology	National Heart, Lung, and Blood Institute/NIH/DHHS	Endothelial Cell Injury by Cytolytic Lymphocytes	07/15/2000	03/31/2002		Award Destroyed	
PT093064	Mitzi Nagarkatti	Microbiology and Immunology	American Heart Association	Role of CD44 in Vascular Leak Syndrome	12/30/1899	12/30/1899		Proposal Not Awarded	
PT093357	Mitzi Nagarkatti	Microbiology and Immunology	National Institutes of Health	Cytotoxic Lymphocytes in Acute Lung Injury				Proposal Not Awarded	
PT093395	Mitzi Nagarkatti	Microbiology and Immunology	National Institutes of Health	Cannabinoids as Novel Anticancer Agents	12/30/1899	12/30/1899		Proposal Not Awarded	
PT094210	Mitzi Nagarkatti	Microbiology and Immunology	Eli Lilly	Contract Work for Eli Lilly Investigation of Anti-huFasL Ab Properties			RED	Proposal Not Awarded	

# Faculty Retirement

- As a condition of beginning retirement distributions from a qualified plan, the IRS requires a **bona fide complete separation** from service with the employer that sponsored the plan.
- In the case of VCU's retirees, the "employer" is considered to be the Commonwealth of Virginia (not just VCU).
- The IRS does not define the length of separation that qualifies as "bona fide" but does make it clear that the separation from service must be complete.
  - VRS regulations require that the separation from service be at least a full calendar month during which the employee would normally work. So in Dr. x case, that month would have been July (since he retired from a 12-month position) but in the case of a 9-month faculty, the separation would not begin counting until the month of September.

# Faculty Retirement

What is a bona fide  
complete separation  
from service?

# Faculty Retirement:

## Bona Fide Complete Separation

- **Severance from Payroll:**

- A complete severance of the employer/ employee relationship would not be limited to a severance from payroll.

- **Termination of existing PI Role(s):**

- If PI continued to perform duties for the university on the grant during the required separation period (one calendar month) that were consistent with the duties of his faculty position (whether paid or unpaid), a bona fide separation probably did not occur.

- **No evidence of agreement to re-hire**

# Faculty Retirement

- OSP needs your help in managing these retirement situations
- Currently we seem to be the last to learn of a faculty member's retirement
- Information comes to us indirectly



# Faculty Retirement

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

## Procedures for Part-Time Employment of Retirees

These procedures apply to the employment of faculty and staff who have retired from Virginia state service through VRS, ORP, and VaLORS. The procedures conform to VCU's retirement plan documents. Failure to adhere to these guidelines can jeopardize the qualified tax status of all VCU retirement plans or may result in the IRS assessing a penalty or excise tax to the retiree. *This process/form is required to be followed only once upon rehire after the initial retirement date.*

### Re-Hire Criteria

- Employment agreements shall not be arranged prior to the retirement date (always the 1st of a month).
- Position duties must not be identical to those performed prior to retirement.
- Re-hire date must be at least 30 days after the retirement date or after a bona fide break in service.
- The re-employment agreement must be for a limited term. The retiree cannot exceed 1,664 work hours annually.

### Eligible Employment Types for Retired State Employees

*Appointments must be temporary and for one year or less in duration.* In addition, departments can hire back former employees only in hourly or adjunct positions.

- Hourly staff (H1 e-class limited to 1,500 hours in a 365-day period and recorded with WAG earn type).
- Adjunct faculty positions (AJ e-class: teaching, research, or public service duties and recorded with account 533140).
- Retirees cannot exceed 1,664 work hours annually.

*Re-employment in permanent part-time faculty or part-time classified staff positions is not an option if the retiree is receiving a retirement benefit.*

# Jeffress Memorial Trust

Changes coming to the administration of the Thomas F. & Kate Miller Jeffress Memorial Trust

- March 1 & September 1 Deadlines
- Outcome of March 1 submission process
- Plans for the future:
  - >Awaiting update from Bank of America

# Sponsored Project Administration Certification Program

- Program runs annually from September-December
- On-line registration will begin later in the summer-will be announced through Research Administration list serve
- Nominal fee charged to cover lunch expenses
- Program is geared toward research administrators with 3 years of experience, but beneficial for those just starting out as well as those experienced in the field

# OSP Surplus Office Supplies

## “Yard Sale”

(at the conclusion of this meeting)

(take what you might need for use at VCU)

(mostly hanging folders and 3-ring binders)

# Office of Sponsored Programs Industry Update

Hospital Employees Conducting Research  
(Clinical Trials)

Melanie Wiggins, Director, OSP-Industry

# Hospital Personnel Conducting Research

## **Discussion Points**

- What are the issues?
- Why does it matter?
- Guidelines

# What are the Issues?

- **Hospital Employees** – OSP Industry is receiving proposals/contracts to negotiate where:
  - (1) hospital employees are named in key roles – e.g., PI, Study Coordinator with budget showing effort.
  - (2) We discover hospital employees will be performing an aspect of a clinical trial where there is no budget information.
- **Growing Trend** - Many industry sponsored clinical trial agreements (especially those using investigational drugs or devices and Master Agreements) include language in the agreement which defines **Study Personnel** as:
  - “Institution (defined as the Virginia Commonwealth University), Investigator (PI) and entities who perform any portion of the study at Institution”
  - “Investigator, all Institution employees, agents and all other persons providing services in the conduct of the Study”



# What are the Issues?

- **The University is the party to the agreement and can only agree on behalf of University employees to compliance obligations** (e.g., abide by University policies, abide by provisions of confidentiality involving sponsor proprietary information, assignment of intellectual property, liability, effort, conflict of interest)
- By using a broad definition of **Study Personnel**, the Sponsor obtains **assurance from the University that everyone performing on behalf of University has the responsibility to comply with University obligations** in the same manner as the University and that the University will be responsible to ensure that all such personnel comply.
- **Assessment of Level/Type of Support: Service provider through hospital affiliation or Study Personnel with associated charges on study?**  
Cath Lab Technician vs. PI or Study Coordinator

# Why Does it Matter?

- **Compliance with University policies**

**VCU Intellectual Property (IP) Policy** - ownership vests with University. University may assign ownership to Sponsor in a separate agreement. The Hospital does not have an IP policy. Hospital employees do not have to comply with University IP policy unless specifically stated in their employment contract (e.g., Residents/Housestaff appointed through the Graduate Medical Education Office must abide by both Health System and University Policies).

VCU does not have the right to assign for hospital employees without their permission. This involves documentation with their signature agreeing to either abide by University obligations (with respect to ownership and assignment) or (if required by Sponsor) to assign directly to Sponsor.

- **Compliance with Cost Accounting Regulations**— no current mechanism for hospital employees to certify effort. Cannot be named on a project if there is no ability to certify effort. University would not be in compliance with cost accounting policies. Audit risk.

- **Compliance with Sponsor obligations**

Obligation of confidentiality for proprietary information received from Sponsor and arising from the conduct of the clinical trial usually for five years from the expiration of the Agreement.

# Current and Emerging Guidelines

- Hospital Employees cannot act as the PI unless there is a paid University appointment. They cannot certify effort or assume fiduciary responsibilities on behalf of University unless they are a University employee.
- Hospital employees performing services only on clinical trials (or other research) in their capacity as a hospital employee (such as Cath Lab Technicians, floor nurses, etc.) are covered under the Affiliation agreement between the Health System and the University. Not charged to specific research.
- Hospital employees (without a paid University appointment) performing services in the role of study coordinator or other study personnel roles should be charged against the project as a service line and not specifically named.

# Current and Emerging Guidelines

- Director, OSP-Industry met with General Counsel from University and Hospital along with School of Medicine representatives to discuss issues related to hospital employee involvement in the conduct of research and the consistent handling of associated paperwork.
- Discussion with General Counsel about a hospital IP policy.
- OSP is developing guidelines and template agreements (for hospital employee signature) based on the particular Sponsor requirements (e.g., Subinvestigator Agreement for GME residents/fellows; Intellectual Property Assignment and Confidentiality Agreement).
- Continuing discussions about effort certification ...



Research Administrators and Compliance Meeting 5/23/2012

# **Update From G&C**

## **Accounting/Effort Reporting**

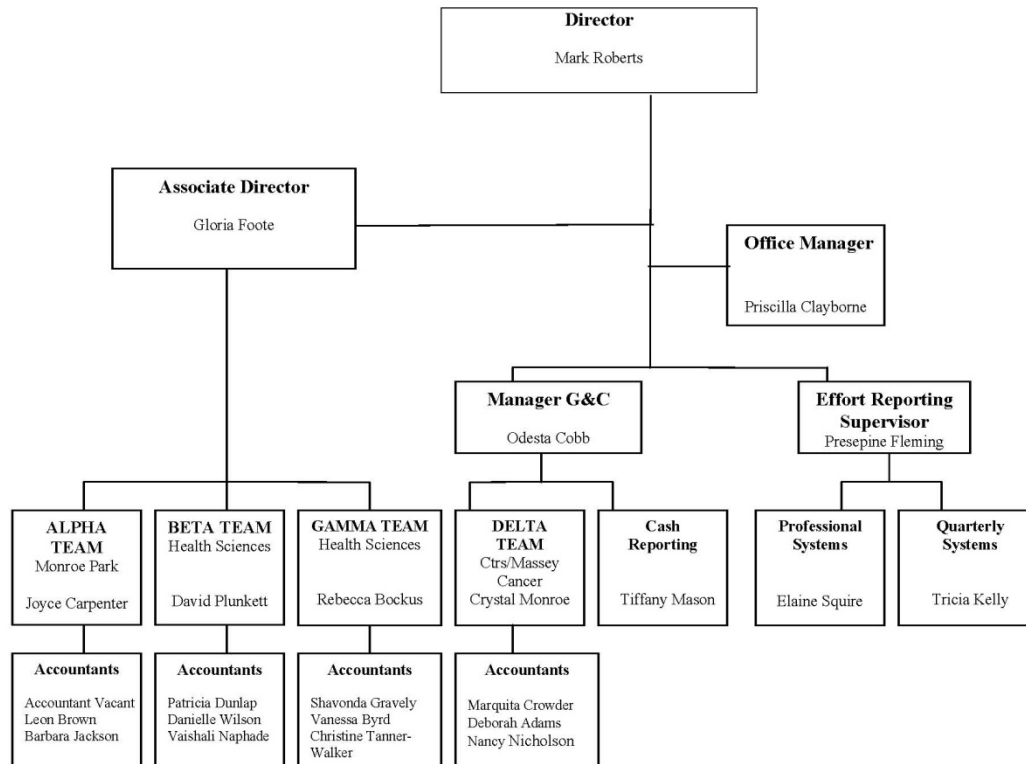
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# New Cash Compliance Coordinator

- Tiffany Mason replaced Suzanne Kight as the G&C Cash Compliance Coordinator effective 5/8/2012 .
- Grant Accountant ALPHA Team – New hire expected in June.
- Contact ALPHA Team Leader Joyce Wimberly (8-5764), or Associate Director Gloria Foote (8-5758) with grant questions if Tiffany Mason is listed as Grant Accountant.

# Revised Org Chart...

VCU Grants and Contracts Accounting & Effort Reporting  
Organization Chart as of 5/23/2012





# Current and Future Initiatives

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- ECRT upgrade to release v4.1
- Policy review in accordance with the Integrity and Compliance Office Policy Program
- Working with Controller to address process changes needed for Dashboard project
- Year end reporting, Banner Fund account balance cleanup, Closing actions on terminated indexes/funds

# Initiatives continued.....

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- G&C staff are participating on Finance and Administration Teams to further improve processes, communications, outreach, people development, and best practices
- Review the G&C Customer Satisfaction Survey report to determine what is important to you and to establish possible new performance measures.

# 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.....

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- Please use the available Banner reports, ePrint reports, and VCU Reporting Center reports to reconcile your grants monthly  
**(This is a VCU university wide requirement)**
- **Compliance is every employee's responsibility**

# Reminders continued....Fiscal Responsibility

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Fiscal managers should:

- Frequently review the expenditure of funds to ensure that they are used in the most effective manner to achieve the mission of the department and the University
- Exercise the closest personal supervision practical over the entire fiscal process
- Monitor budgets

# Reminders continued....Fiscal Responsibility

- Please refer to the responsibility matrix that is on the Fiscal Handbook web site for a list of policies and procedures that every fiscal manager should understand

<http://www.controller.vcu.edu/handbook/Roles.html>

# Thank You

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- 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.
- Contact G&C Helpline at 804-828-8104





# Effort Reporting Updates & Reminders

RACM May 2012



# Agenda

- ECRT Upgrade- Enhancements
- ECRT Upgrade- Planning
- Reminders



# ECRT Upgrade- Enhancements

- Displaying Data and Items Requiring Action
- System Generated Emails and Alerts
- Manage the “Certify Checkboxes” column
- Reporting
- Inquiry/Look-up
- System Availability



# ECRT Upgrade- Planning

- Scheduled
  - May- August 2012
- Feedback
  - Survey (Effort Coordinators)
- Training
  - Fall 2012
- Preparing for the Upgrade

# Reminders

- Important Dates

Type	Certification Period	Certification Start Date	Certification Due Date
Quarterly	12-10-11 to 03-09-12	4/15/2012	6/14/2012
Semester	12-25-11 to 05-09-12	6/15/2012	8/14/2012
Quarterly	03-10-12 to 06-09-12	7/15/2012	9/14/2012
Semi-Annual**	12-10-11 to 06-09-12	8/22/2012	10/21/2012

- General Reminders

- Proactive Reviews (5-28-12 and 06-25-12)
- Processing ECRT Cards
- Other



**THANK YOU**