Research Administration and Compliance Meeting Thursday, April 24, 2014, 1:00 – 3:00 p.m. Larrick Hall, Court End Ballroom A

Agenda

Controller's Updates

FY15 Fringe Rate

Integrity and Ethics Updates (ORIE)

AIRS Annual Update

Clinical Research Services Updates (CRS)

OnCore Update

Sponsored Programs Updates (OSP)

- Staff Update
- OMB Uniform Guidance (with Mark Roberts)
- Updated NIH/AHRQ Policy on Resubmissions
- RAMS-SPOT Status

Grants & Contracts Updates (G&C)

- Staff Update
- ARMICS Forms
- Audit by Assurance Services

Research Administration and Compliance Updates (ORAC)

- Federal Whistleblower Protection Pilot Program
- Final Report Retention
- Controlled Substance Reverse Distribution
- VA-SRA Chapter Meeting, May 16
- Next Year's Meetings

Upcoming Financial Interest Report (FIR) Annual Update in AIRS (due July 1st)

COI Program

4/24/2014

Upcoming Financial Interest
Report (FIR) Annual Update in

AIRS

(due July 1st)

ALREADY?

COI Program

4/24/2014

Annual FIR Updates due July 1

First AIRS notice to all Research FIR users:

5/19/2014 Monday

Annual Update reminder from VPR after 5/19/2014

- To non-completers:
 - ☐ AIRS notice every other Monday (starting 5/19)
 - \square AIRS notice on 7/1/2014 due date
 - ☐ AIRS overdue notice every subsequent Monday til end of July

No on-time completion by July 1st?

- AIRS review cannot occur; COI disposition cannot be conferred
- Protocol or proposal does not progress

 On July 1st, FIR update must be dated 5/19/2014 or later.

Considerations for the Annual Update

- The Annual Update period is open after the first email from AIRS.
- Enter AIRS at https://airs.research.vcu.edu.
- From outside VCU, you must first access the VPN (https://vpn.vcu.edu).
- When inside the AIRS, click to open or edit your FIR.
 - **Method 1**: When your FIR is in the State 'Open for Edits', click the 'Edit Financial Interest Report' button.
 - **Method 2**: If your FIR is in the 'Active' State, click 'Open My Financial Interest Report for Editing' under My Activities.
- You must enter the AIRS to update your FIR even if you have nothing to update.**

 Remove (delete) Financial Interests from your FIR if dates are over a year from the date on which you are updating (unless required to do the Statement of Economic Interests).

Example: If you received payment on March 16th, 2013 for consulting and today is May 20th, 2014, you should delete the March payment from your FIR.

 If you are removing all interests in one category, you must delete each interest BEFORE changing your response to "no" in the particular category. When you are finished with your update, check the box indicating your update is complete AND click Finish.

Your FIR state then moves to 'Active.'



 If you are getting Annual Update reminders after you did your Update, your FIR state is 'Open for Edits.' Go back to your FIR and click through to Finish. Check to ensure your FIR state is 'Active' BEFORE contacting AIRS@vcu.edu for assistance.

How to ensure a timely FIR update:

 Make sure the 'Research FIR' box is checked on the FIR SmartForm (only 'Research FIR' users get the AIRS update email)

1.0 * Which of the following forms were you asked to create or complete?

☑ Research Financial Interest Report

☐ Statement of Economic Interest

Pay attention to email from AIRS.

 The Annual Update must be within a year of last year's update.

Example:

Last year's annual update occurred 6/5/2014.

This year's annual update must be before 6/5/2014 but on or after 5/19/2014.

 Annual Updates cannot be done before 5/19/2014!

Reminders about AIRS

 FIR must be updated within 30 days of a change in your Financial Interests and/or research relatedness.

- PI designates 'COI investigator'
 - Always the PI;
 - Always a student investigator if a student initiated project

For questions about the FIR or FIR updating

Go to <u>Instructions on how to use the VCU</u>
 <u>Activity and Interest Reporting System</u>
 (AIRS) or contact AIRS@vcu.edu

Update on Centralization of VCU Enterprise Clinical Research Administration

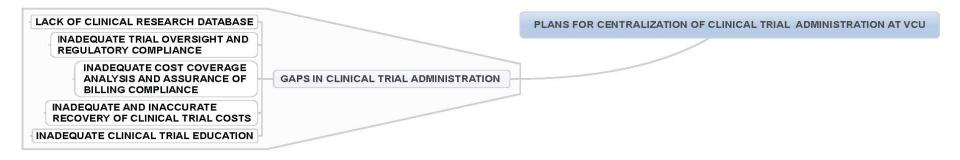


Research Administration and Compliance Meeting
April 24, 2014
Fredika M. Robertson, Ph.D..
Executive Director, Clinical Research Services
Professor, Internal Medicine,
Division of Hematology, Oncology and Palliative Care

Clinical Trials At VCU Background

- Patient-oriented clinical research has been and continues to be a foundation of the VCU research enterprise
- Clinical trials are an increasingly important component of the clinical research effort at VCU.
- VCU is committed to the expansion of our clinical research infrastructure to ensure:
- -enhanced development and recruitment into Phase 1 and 2 clinical trials
- Strict adherence to good clinical practices
- Strict adherence to federal regulatory guidelines regarding clinical research

State of Clinical Trial Enterprise at VCU



Source: White Paper

VCU Enterprise Wide Clinical Trials: Improving Quality, Efficiency and Compliance

Allen D, Ripley E, Coe A, Clore J. Reorganizing the general clinical research center to improve The clinical and translational research enterprise. Eval Health Prof. 2013 Dec;36(4):492-504. doi: 10.1177/0163278713500302. Epub 2013 Aug 19.

Overall Goal: Establish Centralized Administration of VCU Enterprise-Wide Clinical Trials

Goal: Implement strategies to improve quality, efficiency, clinical trial training, compliance, appropriate and accurate fiscal oversight, recovery of clinical trial costs, and visibility of clinical trials at VCU

Purposes:

- Provide consistency across institution for all clinical trial activities
- Provide infrastructure for clinical research programs
- Provide central point for collaboration for clinical and translational research

Overall Goal: Establish Central Administrative Oversight Organization For VCU Enterprise-Wide Clinical Trials

Goal #1: Establish Clinical Research Advisory Board (CRAB) For Clinical Research Oversight And Compliance

Goal: Establish CRAB

Purposes:

- Provide recommendations for clinical research policy and procedures
- Serves as a conduit of information for dissemination of clinical research program information throughout the institution
- Improve efficiency, oversight, and management of clinical research programs

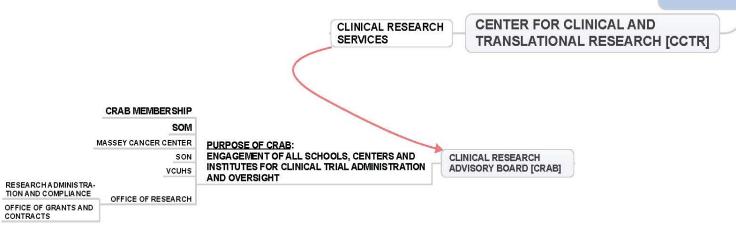
Goal #1: Establish Clinical Research Advisory Board (CRAB)

Benefit: All stakeholders within enterprise wide VCU clinical research programs

CRAB Composition:

- CCTR/CRS Executive Director and staff
- Office of Research [human subjects, compliance, pre/post award]
- Massey Cancer Center, Schools of Medicine, Nursing, Dentistry, Pharmacy, other VCU units with interests in clinical research
- Representatives of VCU clinical research professional organizations – Members of Clinical Coordinator Council, VCUHS

PLAN FOR CENTRAL CLINICAL TRIAL ADMINISTRATION



Goal #2: Organize and Enhance Clinical Trials Education

Goal: Establish a centralized coordinating body for all clinical trial training at VCU

Purpose: Ensures consistency of clinical trials education across VCU

Benefits: All stakeholders in VCU clinical research

Goal #2: Organize and Enhance Clinical Trials Education

Implementation:

- Roll out of Clinical Trial Management System (CTMS) —
 OnCore™ (Online Collaborative Research
 Environment) training across VCU currently in place at
 Massey Cancer Center and SOM
- Clinical coordinator engagement and training for OnCore
- Clinical trials compliance training- Office of Research/Sue Robb, Betsy Ripley

Future Goal #3: Clinical Trial Budget and Cost Coverage Standardization

Goal: Develop training programs and infrastructure for fiscal oversight of enterprise wide clinical research programs

Purpose: Ensures consistency for budget and cost recovery; ensures accuracy of effort reporting

Benefits: All stakeholders involved in VCU clinical research programs

Clinical Research Services

Goal #3: Clinical Trial Budget Standardization

Implementation:

- Budget development training (including Medicare cost analysis, effort allocation, and budgeting basics)
- Accurate effort certification
- Standardization of costs
- Standardize budget negotiation
- Post-Award financial management
- Stabilize internal cost recovery

3 Year Vision For VCU CCTR/CRS

Enhance Visibility of VCU Clinical Trial Excellence

- Enhance visibility of VCU CCTR/CRS as a Center of Clinical Research Excellence to promote sponsored clinical trials and increase diversity of investigator initiated clinical trials
- Leverage strengths of VCU basic, translational and clinical research to develop novel clinical trials

3 Year Vision For Enhancing VCU Clinical Research

- Exploit areas of excellence at VCU matched with emerging therapeutics
- Addiction/substance abuse
- Oncology
- Metabolomics/diseases of metabolism (i.e. cancer/diabetes/polycystic ovary syndrome and insulin resistance)
- Gastroenterology, hepatology and nutrition
- Pauley Heart Center and cardiovascular research
- Women's Health Issues preterm birth, preeclampsia (hypertension in pregnancy) and ovarian function
- Health disparities research
 - high risk for adverse pregnancy outcomes with associated neonatal morbidity and mortality rates in AA women

Enhance Visibility of VCU Clinical Trial Excellence

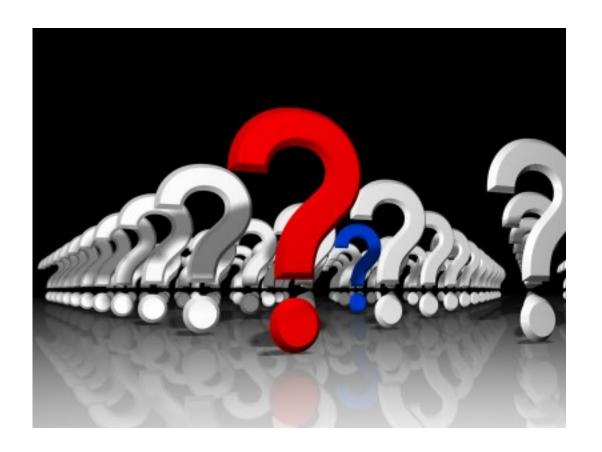
- Enhance innovation in VCU enterprise wide clinical trials and increase utilization of technology
- Leverage decreasing cost of genomics/proteomics for development of novel biomarker trials/newly emerging therapeutic areas
 - New opportunities based on the FDA expectation for in tandem development of diagnostic and novel therapeutics

Enhance Visibility of VCU Clinical Trial Excellence

 Increase/improve interface and networking with pharma/biotech to co-develop innovative sponsored clinical trials/leverage support for basic and translational research leading to further clinical trials

Implementation:

- Identify areas of excellence/expertise, utilize networks of pharma-based investigators and medical liaisons
- Pharmaceutical-Academic Medical Center Strategic
 Partnerships –Supports Efficiencies, Innovation





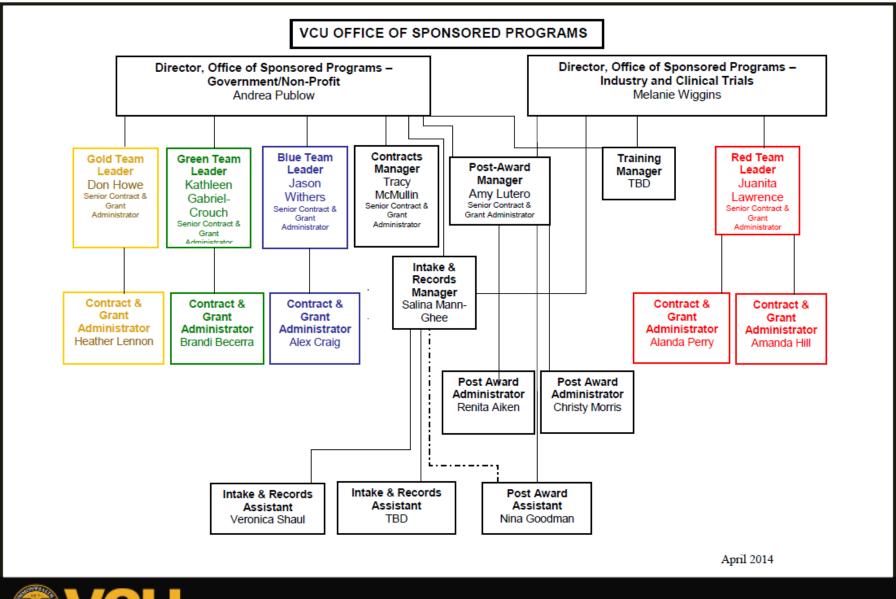
Research Administration & Compliance Meeting
April 24, 2014
Annie Publow, Director, OSP,
Government/NonProfit

OSP Updates

Presentation Topics:

- OSP Staffing Update
- OMB Uniform Guidance
- Updated NIH/AHRQ Policy on Resubmissions
- RAMS-SPOT –
 Development/Implementation Status







OMB Uniform Guidance

- Uniform implementation date for all federal agencies: December 26, 2014
- Date applies to all requirements except audit. The audit regulations become effective the first fiscal year after implementation, so July 2015 given our July-June fiscal year.
- Every federal agency must submit their implementation plan to OMB June 2014



"Uniform Guidance" will replace:

A-21, A-50, A-87, A-89, A-102, A-110, A-122, A-133

OMB Circular A-21: Cost Principles for Educational Institutions (5/10/2004)

OMB Circular A-110: Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (09/30/1999)

OMB Circular A-133: Audits of States, Local Governments, and Non-Profit Organizations (06/26/2007)

OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Government (05/10/2004)

OMB Circular A-102: Grants and Cooperative Agreements with State and Local Governments (10/07/1994)

OMB Circular A-122: Cost Principles for Non-Profit Organizations (05/10/2004)

OMB Circular A-50: Audit Followup (09/29/1982)

OMB Circular A-89: Catalog of Federal Domestic Assistance (08/17/1984)



Section In OMB Uniform Guidance: Cost Principles, Audit, an	ıd
Administrative Requirements for Federal Awards	
Subpart A - Acronyms and Definitions	
Subpart B - General Provisions	
Subpart C - Pre-Federal Award Requirements and Contents	of
Federal Awards	
Subpart D – Post Federal Award Requirements	
Standards for Financial and Program Management	
Property Standards	
Procurement Standards	
Performance and Financial Monitoring and Reporting	
Subrecipient Monitoring and Management	
Record Retention and Access	
Remedies for Noncompliance	
Closeout	
Post-Closeout Adjustments and Continuing Responsibilitie	s
Collection of Amounts Due	
Subpart E – Cost Principles	
General Provisions	
Basic Considerations	
Direct and Indirect (F&A) Costs	
Special Considerations for States, Local Governments and	Indian
Tribes	
Special Considerations for Institutions of Higher Education	1
General Provision for Selected Items of Cost	
Subpart F — Audit Requirements	
Audits	
Auditees	
Federal Agencies	
Auditors	
Management Decision	
Appendices	

Organizational Overview of Uniform Guidance

Appendices
Appendix I – Full Text of Notice of Funding Opportunity
Appendix II – Contract Provisions for Non-Federal Entity
Contracts Under Federal Awards
Appendix III – Indirect (F&A) Costs Identification and Assignment,
and Rate Determination for Institutions of Higher Education (IHEs)
Appendix IV — Indirect (F&A) Costs Identification and
Assignment, and Rate Determination for Nonprofit
Organizations
Appendix V – State/Local Government and Indian Tribe – Wide
Central Service Cost Allocation Plans
Appendix VI – Public Assistance Cost Allocation Plans
Appendix VII – States and Local Government and Indian Tribe
Indirect Cost Proposals
Appendix VIII - Nonprofit Organizations Exempted from Subpart
E: Cost Principles
Appendix IX – Hospital Cost Principles
Appendix X – Data Collection Form (Form SF-Sac)
Appendix XI – Compliance Supplement
<u> </u>



Council on Financial Assistance Reform "COFAR"

COFAR website: https://cfo.gov/cofar/

 Excellent source of information, webinars,
 FAQs, and "crosswalk" documents for understanding the changes



VCU's follow up

Committee on the Administration of Research subcommittee appointed to evaluate Uniform Guidance and make recommendations for implementation at VCU

- ➤ Led by Annie Publow and Mark Roberts
- CAR member participation by Stacey Garnett (SoN), Robert Houlihan (Massey Cancer Center), Brigette Pfister (College of Humanities & Sciences), Margaret Poland (School of Dentistry), Tricia Zeh and Margaret Phillips (School of Medicine), Sandra White (Purchasing)



VCU Approach

- Evaluating existing circular requirements with VCU existing policies, procedures and responsible parties and identifying the areas changing or staying the same
- Utilizing advisory/professional resources:
 - Council on Government Relations (COGR)
 - National Council of University Research Administrators (NCURA)
 - Society of Research Administrators (SRA)
 - Huron Consulting
- Involving VCU stakeholders as needed
- Providing updates to CAR and RACM
- Updating training materials and/or creating new



Updated NIH/AHRQ Policy on Resubmissions

Background

During the **Enhancing Peer Review initiative**, the NIH and AHRQ reduced the number of allowable resubmission applications from two to one (NOT-OD-09-003; NOT-HS-10-002), and stipulated that any subsequent submission for that project must demonstrate significant changes in scientific direction compared to the previous submissions. Those policies were implemented to address the growing trend for resubmission applications to be scored more favorably, which in essence created a queue for meritorious applications before success in funding. In this extended period of tight funding, this approach resulted in many meritorious research applications being deemed ineligible for additional submissions, and many investigators having to propose substantial changes to productive research programs. New Investigators may have been significantly affected because new research directions may be quite difficult during this phase in their careers.

See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html#sthash.2ltJQ6d7.dpuf



Updated NIH/AHRQ Policy on Resubmissions

NOT-OD-14-074 and NOT-OD-14-082

"Effective immediately, for application due dates after April 16, 2014:

- Following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate due date.
- The NIH and AHRQ will not assess the similarity of the science in the new (A0) application to any previously reviewed submission when accepting an application for review.
- Although a new (A0) application does not allow an introduction or responses to the previous reviews, the NIH and AHRQ encourage applicants to refine and strengthen all application submissions."
- See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-082.html#sthash.vbWrg58m.dpuf



Updated NIH/AHRQ Policy on Resubmissions

NOT-OD-14-074 and NOT-OD-14-082

Options

The updated policy allows an investigator to submit a new (A0) application following an unsuccessful resubmission (A1) application. The updated policy has no time limit between an unsuccessful resubmission (A1) application and a subsequent, new (A0) application, or between an unsuccessful new (A0) application and a subsequent new (A0) application. The time limit of thirty-seven months between an unsuccessful (A0) application and the subsequent resubmission (A1) application does remain in effect. The number of submission cycles is not limited, but NIH encourages applicants to update their applications to reflect the status of the field over the interim period and to incorporate new preliminary data, literature citations, letters of reference, etc. as time passes. The updated policy does not preclude submission of a new (A0) application following an unsuccessful new (A0) application, without an intervening resubmission (A1) application.

- See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-082.html#sthash.vbWrg58m.dpuf



RAMS-SPOT

Research Administration Management System-Sponsored Programs Online Tracking

- Database for sponsored projects administration and submission (Vendor= Click Commerce)
- Will replace "VCUeRA" (Vendor=InfoEd)
- Internal discussions began early 2013
- Currently in development
- All records will be electronic



RAMS-SPOT Implementation Timeline

- Phased approach to implementation
 - Proposal submission functionality to transition first
 - Awarding capability to follow
- Affect of Fall 2013 Federal Closure- "Silver Lining"
 - Planned Grants.gov forms change scheduled for January 2014 (which would have required InfoEd upgrade) was cancelled
 - Eliminated our need for short term but time consuming actions in InfoEd
 - Allowed us to stay focused on development discussions

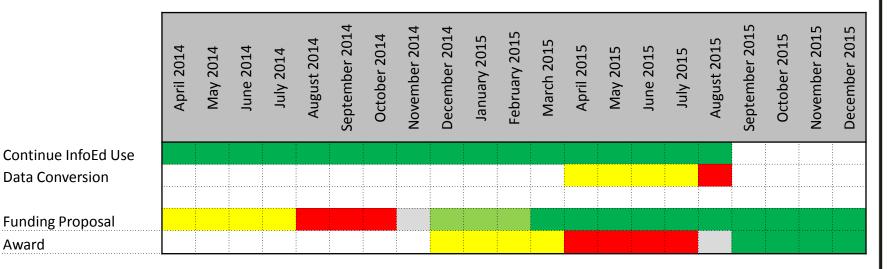


RAMS-SPOT Implementation Timeline

- Two phased implementation
 - –Phase 1: Submission of all new of funding proposals
 - Includes all proposals including available Grants. Gov opportunities, industry agreements, Master agreements, Confidentiality Non Disclosure Agreements (CDA), & Letters of Intent (LOI) that require OSP signature/submission
 - Pilot Testing: December 1, 2014 February 28, 2015
 - Go Live: March 1, 2015
 - —Phase 2: Awards and Post Award activities
 - Go Live: September 1, 2015
 - Basic award data from InfoEd will be imported into RAMS-SPOT
 - InfoEd system of record for FY2015 (ending June 30, 2015)
 - RAMS-SPOT system of record for FY2016 (July 1, 2015-June 30, 2016)



SPOT Implementation Timeline



Pilot Test In Production Development Testing **Training**



Award



Research Administration and Compliance Meeting

April 24, 2014

Grants & Contracts Accounting Updates

G&C staff and misc. updates

- Shavonda Gravely is new Gamma Team Leader
- 90 Day Notice memo under revision
- G&C ARMICS forms on VCUHS
 https://www.pubapps.vcu.edu/vphs/portal/
- G&C Audit by Assurance Services



VCUQ Effort Reporting

Primary VCUQ employees will be included in the ECRT system and require certification each effort reporting period, effective with the Summer period which will include the pay period starting 5/10/2014.



FY14 G&C Audit 7/1/13 -2/28/14

#	Documentation Requested	Date Requested
1	G&CA Daily Check Logs (including copies of payments and invoices, Banner screen prints, deposit tickets and receipts) for the following dates: July 25, 2013, October 1, 2013, November 22, 2013, January 31, 2014, and February 4, 2014	4/16/2014
2	Quarterly Suspense Account Reconciliations for Q1 (September) and Q2 (December) of FY 2014	4/16/2014
3	A/R Aging Reports and all associated communications of overdue billings with grant or contract entities (Past Due Notices) for the months ending July 31, 2013, December 31, 2013, and February 28, 2014	4/16/2014
4	List of federal grants / contracts whose period of performance concluded during the audit period	4/16/2014
5	List of non-federal grants/contracts whose period of performance concluded during the audit period	4/16/2014
6	Final Monthly Grant Deficit Reports for the months ending July 31, 2013, November 30, 2013, and January 31, 2014 and all communications with departments regarding deficits for those months (emails, memos, support, department responses, and other follow-up)	4/16/2014



FY13 vs FY14 Sponsored Project Expenditures

VCU Expend. at 3/31/2013 - \$ 127,841,395.40

VCU Expend. at 3/31/2014 - \$ 128,697,984.74



Questions???

Thanks for your continued assistance.

Grants and Contracts Accounting/Effort Reporting

Mark Roberts





Research Administration

And Compliance Update

April 24, 2014

Federal Whistleblower Protection Pilot Program

- 41 USC 4712
- Additional Protections for Employees
- Four Year Pilot Program until January 1, 2017
- Effective July 1, 2013



Purpose

- Employers cannot discharge, demote or otherwise discriminate against an employee for disclosing any of the following:
 - Gross mismanagement of a federal contract or grant
 - Gross waste of federal funds
 - Abuse of authority relating to a federal contract or grant
 - Arbitrary and capricious exercise of authority that is consistent with the mission or successful performance
 - Substantial and specific danger to public health or safety
 - Violation of law, rule or regulations related to a federal contract or grant



Application

- Employees working on a federal grant or contract disclose to
 - Member of Congress or a representative of a committee of Congress
 - An Inspector General
 - The Government Accountability Office
 - A federal employee responsible for oversight or management
 - An authorized official of the DOJ or other law enforcement agency
 - A court or grand jury
 - A management official or other employee of VCU who has the responsibility to investigate, discover, or address misconduct



Protections

- If discharged, demoted or otherwise discriminated against, employees can, within three (3) years of the reprisal, file a complaint with the Inspector General.
- Investigation
- Report issued within 180 days



Findings

- If sufficient basis the complainant has been subjected to a prohibited reprisal
 - Order the contractor or grantee to take affirmative action to abate the reprisal
 - Order the contractor or grantee to reinstate the person to the position previously held, provide compensatory damages (including back pay), benefits, etc.
 - Order the contractor or grantee to pay the complainant an amount equal to the aggregate amount of costs and expenses



Responsibility and Actions

- Notify each employee working on a federal grant or contract in writing of the availability of these extra protections
 - E-mail to all faculty, staff and students from Dr.
 Macrina semi-annually during four year pilot
 - Information posted on our website
 - Incorporation into our Duty to Report policy
 - Discussion at mandatory staff orientation sessions



Final Report Retention

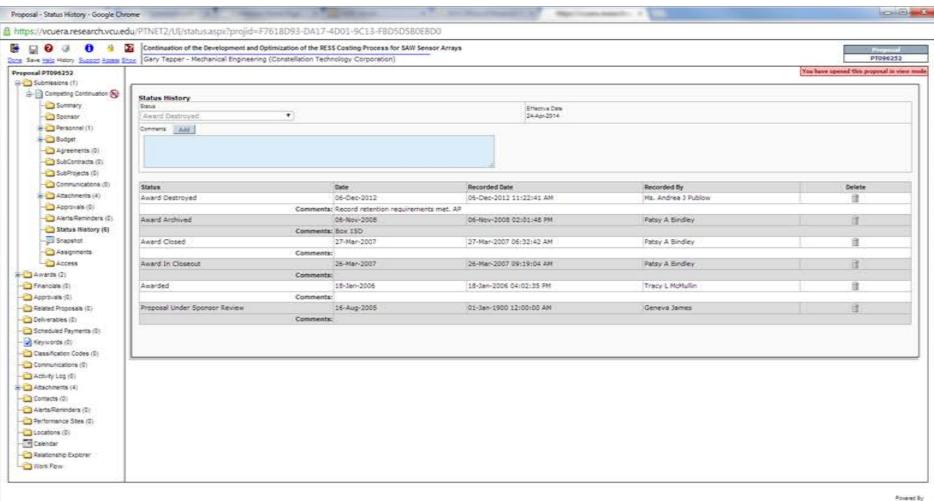
- Meeting with Library representatives
 - New system open access
- Review of the requirement:
 - Research: Final Reports This series documents
 the completion of research by a college or
 university employee. This series may include, but
 is not limited to: final scientific or research report
 of results. Permanent, In Agency retention.



Analysis

- Final Scientific and Technical Reports
 - May contain Sponsor proprietary information
 - Less than full access
 - Library system would not meet the requirements
 - OSP would be less than successful obtaining final technical reports





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Next Steps

- Determination from Assurance Services that Status History meets the requirement (received)
- Determination of how these reports will be stored
- Incorporate into the existing closeout process

Expectation

- Principal Investigators will continue to retain for five years after last action
 - Notes, Work Papers and Technical Data
 - This series documents the data collection for a program/research project conducted by a college or university employee. This series may include, but is not limited to: notes, notebooks, drawings, work papers, technical data, experimental results, statistics, findings, and conclusions.



Controlled Substances: Reverse Distribution

- Registrations continue 40 or so
- Disposal of Substances
- Met with Guaranteed Returns
 - Reverse distributor for VCUHS
 - Monthly visits
 - Working with them to incorporate "pick-up" of substances from our Registrants
 - More to come later



Next Month and Next Academic Year

- VA SRA Chapter Meeting
 - Friday, May 16, 2014
- Watch for Announcement and Web Update for Next Year's Schedule in mid-May

