Research Administration and Compliance Meeting Wednesday, October 28, 2015 1:00 – 3:00 p.m. Larrick Student Center, Court End Ballroom A

Agenda

Grants & Contracts

- Status of HHS Transition to Subaccounting
- Overview of Upcoming Cost Share Brown Bag Topics
- G&C Updates

Office of Export Compliance

- Dual Use Research of Concern Update
- Visitors to Campus

Office of Sponsored Programs

- OSP Staffing Update
- RAMS-SPOT—Implementation Update
- Sponsored Projects Administration Certification Program-Spring dates announced
- Uniform Guidance—Subrecipient vs. Contractor determination
- Federal Research Terms and Conditions—Comment Period
- State Agency—"Background check" expenses

Office of Research Administration and Compliance

- FY 2015 Awards Report
- Compliance Notices 15-006 Use of RAMS SPOT
- Compliance Notices 15-007 Nonstandard Terms

Office of Research Subjects Protection

Office of Research Integrity and Ethics

COI Assessment and Process

Clinical Research Updates

- New Chargemaster Rates
- SIP Portal Link (Patient Recruitment Tool)
- Save the Date FDA Workshop April 18, 2016 Larrick Hall

Upcoming RACM Meetings – 1 – 3 p.m., Larrick Student Center, Court End Ballroom A

- February 17, 2016
- April 27, 2016

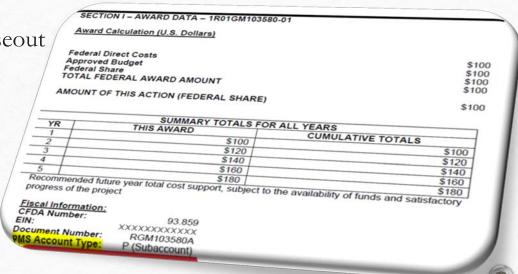






NIH Sub-accounting Transition/Updates

- What is it?
 - Change in how the University is reimbursed for costs occurred on NIH awards
- Why is NIH transiting to Sub-accounting?
 - Improve financial data integrity and financial closeout
 - http://grants.nih.gov/grants/payment/faqs.htm#3777
- When?
 - Initially the Fall of 2013
 - Federal FY 2016 (October 1, 2015 September 30, 2016)
 - NIH's goal completion date: September 30, 2016









NIH Sub-accounting Transition/Updates

- How does it impact departments?
 - Cumulative Reporting (Streamlined Non-competing Award Process (SNAP))
 - A new grant ID create to transition the award
 - Budget Year Reporting (Annual Financial Reporting or Carry-forward approval required)
 - A new grant ID create to transition the award

Virginia Commonwealth University Grants and Contracts Accounting FUND ASSIGNMENT MATRIX BY TYPE OF AWARD [based on Sponsor Financial Reporting Requirement] Award Type Award Conditions Financial Reporting Requirement referred to below as (RR) Federal I)NIH EA/SNAP, NSF, DOE, ONR, USED, NASA, DOD [these are our primary; may include others] unless 2)Annual Financial Reporting or Carry-forward approval required ...thus Budget Period Budget Period Index









NIH Sub-accounting Transition/Updates

- Where can I go for more information?
 - http://www.controller.vcu.edu/grants/gc-admin/fundassignmatrix.pdf
 - http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-103.html
 - http://grants.nih.gov/grants/payment/faqs.htm









Cost Sharing

















Cost Sharing

- Recent inquires received have identified a need for conversation and training on cost sharing
- Upcoming Training
 - Format: 2 one-hour training sessions ("Brown bag")
 - Topics: Session 1: "The Basics" and Session 2: "Documenting Cost Sharing"
 - When: TBD (End of 2015/Beginning 2016)
- We look forward to seeing you!









Thank you!



Contacts (Cost Share Training)

- Cathy Short (804) 828-8104
- Presepine Fleming (804) 828-2056
- Mark Roberts (804) 828-0033

Contacts (NIH Sub-accounting)

- Tiffany Mason (804) 828-5874
- Assigned Customer Service Team (804) 828-8104
- Presepine Fleming (804) 828-2056
- Mark Roberts (804) 828-0033







Export Compliance Update

Quinton Johnson

Director, Export Compliance Office

Office of the Vice President for Research and Innovation

Lab Visitor Guidance

- Is a person a
 - Post-doc
 - Visiting Scholar
 - Volunteer
 - Employee
 - Some other distinction
- If the person has a Visa is it appropriate for their role at VCU
- Who should you contact with these questions



Export Compliance CommitteeMembership Roster

College of Humanities and Sciences	Edith Allin
Fixed Assets	Lynne Trice
Global Education	Paul Babitts
Human Resources	Cathleen Burke & Laurie Bourne
Integrity and Compliance Office	Jacqueline L Kniska
Office of Environmental Health and Safety	Mary Beth Taormina & Larry Mendoza
Office of Procurement	Brenda Mowen & Nick Fetzer
Office of Sponsored Programs	Andrea J Publow & Melanie A Wiggins
Provost Office	Heidi Jack
School of Engineering	Ram B. Gupta
School of Medicine	Tricia Zeh
VCU Qatar	Gary L Huff
VCU Technology Services	Dan Han



Dual Use Research of Concern Review Process: Any individual working with any of the 15 DURC Agents should immediately notify the Institutional Review Entity (IRE) via an expanded Memorandum of Understanding (MUA) The IRE reviews research to determine if it involves any of the 7 experimental effects No Experimental effects involved, the IRE has 30 calendar Experimental effects not involved, the IRE still must notify and has 30 calendar days to notify days to notify the appropriate USG funding agency of the appropriate USG funding agency of the the outcome of the review outcome of the review The IRE considers the previously identified risks and the anticipated benefits in order to develop a draft risk mitigation plan The MUA is appropriately marked and signed by the IRE and the researcher agrees in The IRE works with the USG funding agency to writing to notify the IRE if the research complete the draft risk mitigation plan within 90 changes in a way that would implicate one of calendar days of the IRE's initial determination that the 7 Experimental Effects research is DURC The USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan The IRE and researcher establish a plan for a periodic review of the research moving forward VCU and the IRE implement the approved risk mitigation plan and provide ongoing oversight of DURC

15 DURC Agents & Toxins:

- Avian influenza virus (highpath)
- Bacillus anthracis
- 3. Botulinum neurotoxin
- Burkholderia mallei
- Burkholderia pseudomallei
- Ebola virus
- 7. Foot-and-mouth disease virus
- 8. Francisella tularensis
- 9. Marburg virus
- Reconstructed 1918 influenza virus
- 11. Rinderpest virus
- Toxin-producing strains of Clostridium botulinum
- Variola major virus
- Variola minor virus
- Yersinia pestis

7 Experimental Effects:

- Enhances harmful consequences of agent or toxin
- Disrupts immunity or effectiveness of immunization without clinical/agricultural justification
- Confers resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions or facilitates ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent
- 5. Alters the host range or tropism
- Enhances the susceptibility of a host population
- Generates or reconstitutes an eradicated or extinct agent or toxin previously listed

Contact Information for DURC

Mike Elliott

Senior Safety Engineer
Office of Environmental Health and Safety

- mtelliot@vcu.edu
- 804-400-4984

Larry Mendoza

Sr. Safety Engineer/Chemical Safety
Office of Environmental Health and Safety

- <u>lgmendoz@vcu.edu</u>
- 804-828-2596

Quinton Johnson

Director, Export Compliance Office

- <u>exportctrl@vcu.edu</u>
- qjohnson3@vcu.edu
- (804) 827-6088

VCU Webpage

http://www.research.vcu.edu/export control/



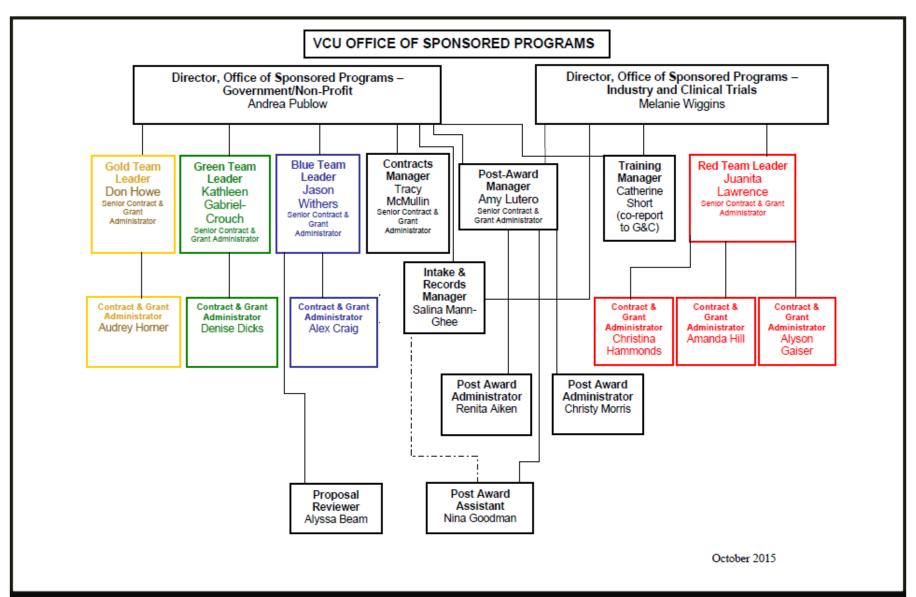


Office of Sponsored Programs (OSP) Updates:
Annie Publow
Director, OSP-Government/NonProfit
October 28,2015

OSP Update Topics

- OSP Staffing Update
- RAMS-SPOT—Implementation Update
- Sponsored Projects Administration Certification Program-Spring dates announced
- Uniform Guidance—Subrecipient vs. Contractor determination
- Federal Research Terms and Conditions—Comment Period
- National Dialogue
- State Agency—"Background check" expenses







OSP-Review Team Priorities Blue, Green, Gold teams

Proposal Review and Submission

Historically #1 priority

Agreement Review and Negotiation Dedicated Contract Manager over past year+ has allowed for better negotiation timelines. Aim to increase resources for further improvement.

Administrative Actions

Historically actions have taken a "back seat" to proposal submissions

Aim to increase resources to reduce wait time for these transactions.



RAMS-SPOT Phased Implementation

Phase 1: Submission new funding proposals

- ➤ Go Live: May 2015 Included...
 - All task orders and new proposals including available Grants.gov opportunities
 - Pre-proposals/Letters of Intent (LOI) that require OSP signature
 - Reviews for Confidentiality Non Disclosure Agreements (CDA),
 Material Transfer Agreements (MTA), and Data Use
 Agreements (DUA), Just-in-Time (JIT), Export Control
 - Agreements for negotiation including Unilateral/Bilateral/Master agreements



Make it real

RAMS-SPOT Implementation Update

Phase 2: Awards, Post Award, Reporting activities

- Includes...
 - Award processing (initial and subsequent actions)
 - Funding Proposal Continuations/Supplements
 - Administrative Actions (Prior Approval, Expanded Authority, Progress Reports)
 - Subaward/Subrecipient (initial and subsequent actions)
 - Closeout
 - Reporting
- Target Go Live: 1st Quarter 2016



	RAMS-SPOT Target Implementat	on T	imeli	ne															
Implementation Phase	Activity	January 2015	February 2015	March 2015	April 2015	May 2015	June 2015	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2015	May 2015	June 2015
	Continue InfoEd Use																		
InfoEd	New Proposals (IAF package)																		
	Continuation Proposals (IAF package)																		
	Awards & Post Award Actions																		
	Data Conversion																		
RAMS-SPOT Phase 1	Funding Proposal (new proposals, pre- proposals and task orders)																		
	Pre-Award Review Projects: Unilateral/Bilateral/Clinical Trial/Master Agreements, CDAs, MTAs, DUAs, JIT, Export Control																		
	Awards-Initial & Subsequent																		
	Awards-Subsequent																		
	Funding Proposal Continuations																		
RAMS-SPOT Phase 2	Post Award Review Projects (prior approval, expanded authority, progress report)																		
	Subawards-Initial & Subsequent																		
	ODS/Dashboard Data Feed																		
RAMS-SPOT	Closeout																		
Phase 3	Reports																		
									V	ersion	2015	-08-2	6						
		Design Work		Pilot Test				Traini	ing										
		Development		Soft Launch				Out o	f Serv	ice									
		Testi	ng			In Pro	ducti	on											



Sponsored Projects Administration Certification Program

Winter/Spring, 2015:

- Sufficient interest expressed to fall survey, program will be offered
- Dates on OSP Training website next week: http://www.research.vcu.edu/osp/training.htm
- Will announce registration for spring via Research Administration list serve

Course updated to include RAMS-SPOT and Uniform Guidance



Uniform Guidance: Subrecipient vs. Contractor Determinations

Award Instrument:

- Grant agreement
- Cooperative agreement
- Contract, or
- Fixed amount award

Federal Awarding Agency

 Could be any of 26 Federal Awarding agencies

Recipient/Non-Federal Entity is also Passthrough entity Could be state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization

 Could be state, local government, Indian tribe, institution of higher education (IHE),hospital nonprofit organization

OR for-profit

Contractor

Award Instrument:

- Contract
- Purchase Order or other
 Procurement

Determination Process

Subrecipient

Award Instrument:

- Subaward
- Subcontract
- Fixed amount subaward
- Could be state, local government, Indian tribe, institution of higher education (IHE), hospital nonprofit organization OR for-profit



Uniform Guidance: Subrecipient Determination

(200.330 Subrecipient and contractor determinations)

- (a) **Subrecipients**. A subaward is for the <u>purpose of carrying out a portion of a Federal award and creates a Federal assistance relationship with the subrecipient</u>. See §200.92 Subaward. Characteristics which support the classification of the non-Federal entity as a subrecipient include when the non-Federal entity:
 - (1) Determines who is eligible to receive what Federal assistance;
 - (2) Has its performance measured in relation to whether objectives of a Federal program were met;
 - (3) Has responsibility for programmatic decision making;
 - (4) Is responsible for adherence to applicable Federal program requirements specified in the Federal award; and
 - (5) In accordance with its agreement, uses the Federal funds to carry out a program for a public purpose specified in authorizing statute, as opposed to providing goods or services for the benefit of the pass-through entity.

- (b) *Contractors*. A contract is for the <u>purpose of obtaining goods and services for the non-Federal entity's own use and creates a procurement relationship with the contractor. See §200.22 Contract. Characteristics indicative of a procurement relationship between the non-Federal entity and a contractor are when the non-Federal entity receiving the Federal funds:</u>
 - (1) Provides the goods and services within normal business operations;
 - (2) Provides similar goods or services to many different purchasers;
 - (3) Normally operates in a competitive environment;
 - (4) Provides goods or services that are ancillary to the operation of the Federal program; and
 - (5) Is not subject to compliance requirements of the Federal program as a result of the agreement, though similar requirements may apply for other reasons.
- (c) *Use of judgment in making determination*. In determining whether an agreement between a pass-through entity and another non-Federal entity casts the latter as a subrecipient or a contractor, the substance of the relationship is more important than the form of the agreement. All of the characteristics listed above may not be present in all cases, and the pass-through entity must use judgment in classifying each agreement as a subaward or a procurement contract.



Uniform Guidance— Subrecipient vs. Contractor determination

Makes independent decisions about scope of work Participates in designing/conducting research Designation of a Principal Investigator Probable intellectual property and/or publications	Scope of Work Budget/budget justification reflecting effort Biosketch(es) for key personnel Consortium letter or face page	Compliance with Sponsor's regulations & requirements (administrative, cost principles, audit) Grant/Contract specific terms & conditions	SUBRECIPIENT
	Scope of Work Budget/budget justification reflecting effort Credentials for important personnel Consortium letter or face page	Compliance with Sponsor's regulations & requirements (administrative, cost principles, audit) Grant/Contract specific terms & conditions	SUBRECIPIENT
and markets services to a range of customers Competes with comparable entities to provide similar goods and services	Price quotation Cost estimate Individuals not named, cost not based on effort SOW includes milestones/ deliverables	Subject to procurement regulations VCU COVA OMB A-110 or Uniform Guidance Appendix II	CONTRACTOR



Federal Research Terms and Conditions—Comment Period



http://www.nsf.gov/awards/managing/rtc.jsp



Federal Research Terms and Conditions—Comment Period

NATIONAL SCIENCE FOUNDATION

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Request for Public Comment

AGENCY: National Science Foundation (NSF).

ACTION: Request for public comment on updated Research Terms and Conditions (RTC) to address and implement the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards issued by the U.S. Office of Management and Budget (OMB).

SUMMARY: In 2000, the Federal Demonstration Partnership (FDP), a cooperative initiative among numerous Federal agencies and institutional recipients of research funds aimed at reducing the administrative burdens

- Standard Terms and Conditions initially developed 2000 FDP as model implementation to OMB A-110
- Terms updated by "Research Business Models" (RBM) in 2005, an interagency working group
- June 2014, RBM interest to "develop a revised set of RTCs as they apply to research and research-related grants
- Sub-set of agencies participating
- Aims: (1) Incorporate UG, supplement select provisions (2) Apply to award or as incorporated by reference. Allow for flexibility....

http://www.nsf.gov/awards/managing/rtc.jsp



Reporting and DATA Act Open Dialogue

Welcome

How to Participate

About Us

DATA Act Resources

*To participate in the dialogue, you can submit a new idea by clicking "Submit New Idea" to the right, or you can vote and comment on existing ideas below.

Grants practices and processes

Key Participants: grantees, cooperative agreement holders, subgrantees

https://cxo.dialogue2.cao.gov/a/idea s/top/campaign-filter/byids/campaigns/13162

What we're discussing [-]

What do these tags mean?

administrative-burden

reporting-burden

reporting-processes

concerning-regulations-or-guidelines

duplicate-reporting

non-standardized-processes

central-reporting-portal audit

frequency-of-reporting

increases-costs

Question: If you could change one thing that would ease your reporting burden associated with your grants or subgrants, what would it be (e.g., time, cost, resource burden)?

Question: If you have reporting requirements to the Federal government, how are those met? (feel free to be specific about what is reported to whom and through what mechanism)

Question: If you could create a central reporting portal into which you could submit all required reports, what capabilities/functions would you include?

OMB circular A-133:

Question: If you could make a change to ease your reporting burden for audits under the Single Audit Act (i.e., audits required by OMB Circular A-133 which is being replaced by the Uniform Guidance 2 CFR 200 Subpart F), what one thing would you change about reporting by the auditee?

Question: If you could make a change to ease your reporting burden for audits under the Single Audit Act (i.e., audits required by OMB Circular A-133 which is being replaced by the Uniform Guidance 2 CFR 200 Subpart F), what one thing would you change about reporting by the auditor?

Question: If you could make a change to ease your reporting burden for audits under the Single Audit Act (i.e., audits required by OMB Circular A-133 which is being replaced by the Uniform Guidance 2 CFR 200 Subpart F), what one thing would you change about reporting to the Federal Audit Clearinghouse?

Uniform Guidance (2 CFR 200):

Question: Are there requirements in the new 2 CFR 200 that need additional clarification for improved implementation with reduced administrative burden?

Question: What are the perceived burdens associated with the new standards such as the documentation of salaries & wages and time & effort (2 CFR 200.430), subrecipient monitoring (2 CFR 200.331), procurement standards (2 CFR 200.317- 2 CFR 200.324)?

Question: How can the administrative burden associated with standards compliance be lowered?



Virginia State Agency-MOA "Background Checks"

Sample language:

The [VA state agency] may require a background check for Contractor staff assigned to any resulting agreement. The Contractor shall be required to pay for all background checks processed for staff assigned to any agreement resulting from this agreement at a rate of \$50.00. Fees are on a per background check basis and will be invoiced by [VA state agency]. The Contractor employees will be required to complete a form granting authority to release information. The Contractor shall allow the [VA state agency] ac review Contractor staff personnel and employment

➤ Recommend including line item in proposal budgets to account for cost of background checks

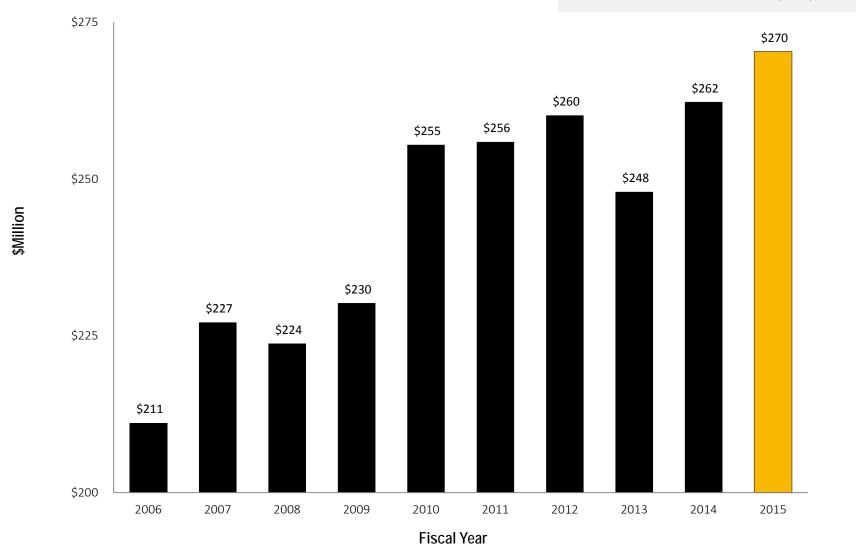




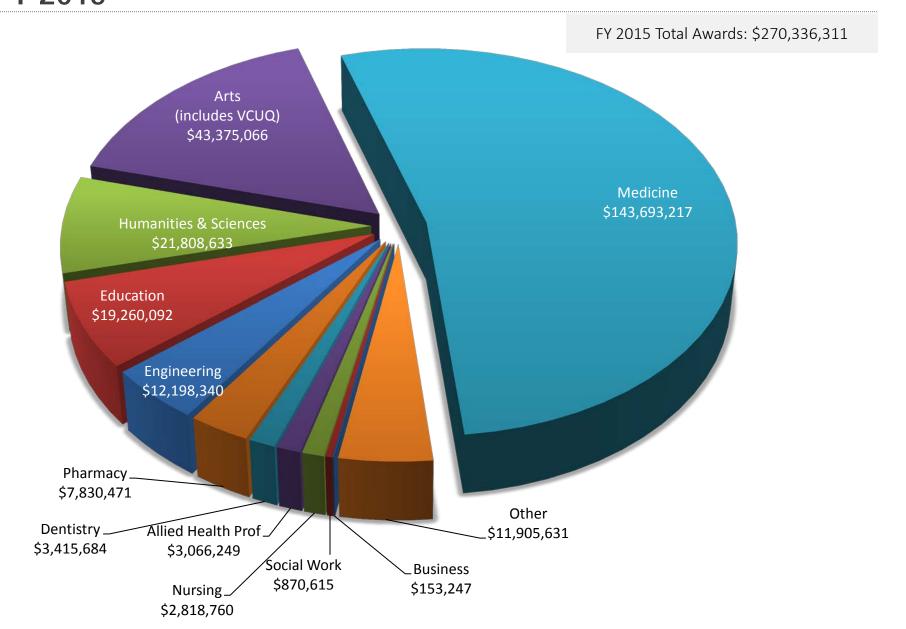
VCU Sponsored Awards Portfolio FY 2015 Office of Research & Innovation

VCU Sponsored Program Awards FY 2006-2015

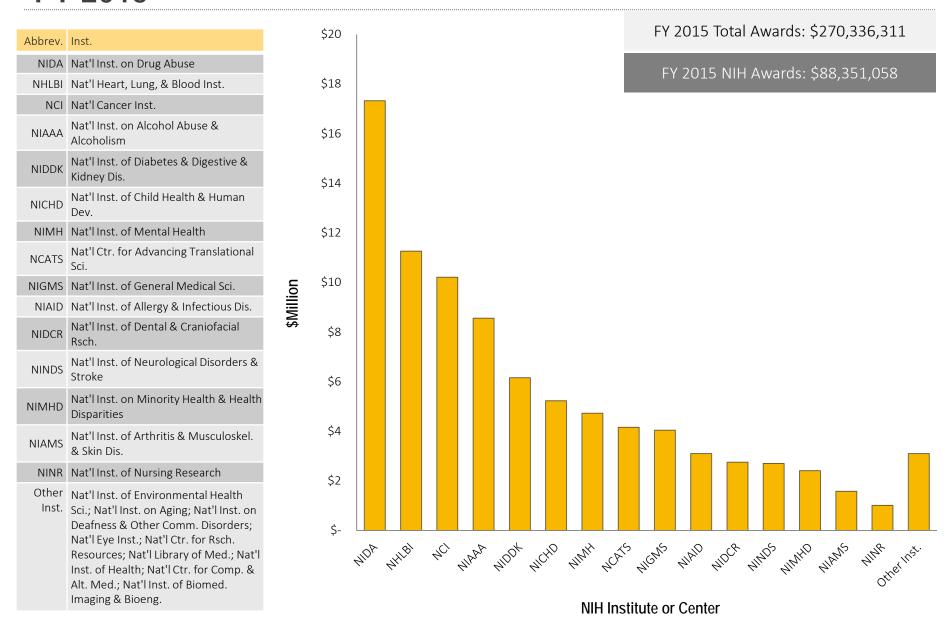
FY 2015 Total Awards: \$270,336,311



VCU Sponsored Program Awards by School FY 2015

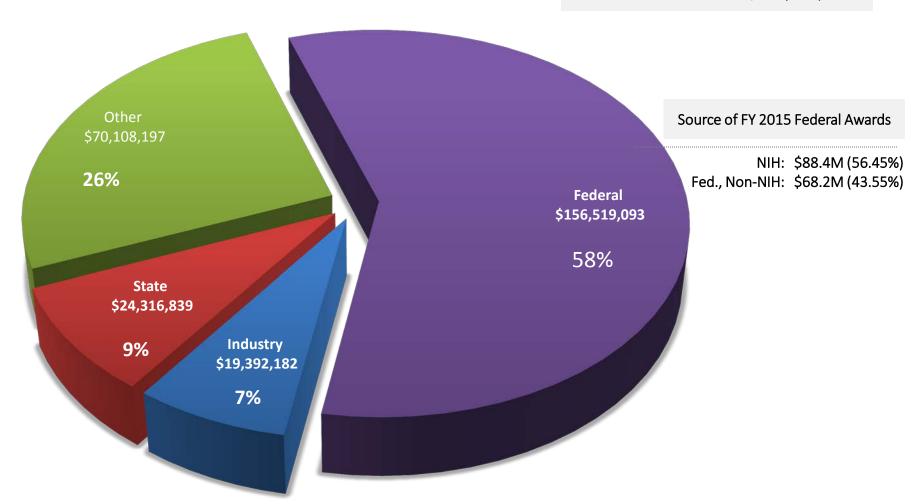


VCU Sponsored Program Awards: NIH Portfolio FY 2015



VCU Sponsored Program Awards by Source FY 2015

FY 2015 Total Awards: \$270,336,311



Compliance Notice

Research Administration and Compliance No. 15-006 October 23, 2015

NOTICE: USE OF RAMS-SPOT

The Office of the Vice President for Research and Innovation, Office of Sponsored Programs, launched the Research Administration Management System – Sponsored Programs Online Tracking (RAMS-SPOT) system in Spring 2015. RAMS-SPOT will allow for paperless routing of all major project transactions, paperless record storage, in-system budgeting, in-system communications and will reduce the need for forms. Investigators and administrators will be able to readily monitor proposal and project review status.

In all cases, the Principal Investigator is responsible for routing a new pre-proposal, proposal, or task order for school and OSP review. PI access is by EID and password; the routing process is the equivalent of a signature.

RAMS-SPOT will be implemented in phases:

Phase 1 - New Funding Proposals and Agreement Review (including Confidential Disclosure Agreements, Master Agreements, Unilateral and Bilateral Agreements, Materials Transfer and Data Use Agreements)

Phase 2 – Awards and Post Award Activities, Closeout and Reporting (former phases 2 and 3 are now conflated)

Effective May 1, 2015, all research, instruction, and other sponsored proposals must be submitted through the RAMS-SPOT system.

Effective September 2, 2015, all sponsored program agreements for negotiation received from VCU internal sources must be submitted using the Submit Document for Review process in RAMS-SPOT.

Additional information on RAMS-SPOT, including implementation plans, get-started guides, and training tutorials can be found at http://www.research.vcu.edu/osp/rams-spot.htm

This Notice will be updated as each Phase is implemented.

Issued by,	
Susan Robb, CRA, CHRC	Date
Senior Associate Vice President	
for Research Administration and C	ompliance

Draft Compliance Notice

Research Administration and Compliance No. 15-007 October 23, 2015

NOTICE: NON-STANDARD REQUIREMENTS IN SPONSORED AGREEMENTS, MATERIAL TRANSFER AGREEMENTS, DATA USE AGREEMENTS OR CONFIDENTIALITY AGREEMENTS

NON-STANDARD TERMS

In some circumstances, when the terms of a sponsored agreement, material transfer agreement, data use agreement or confidentiality agreement (hereinafter "agreements") deviate from the accepted policies or practices of the University but do not violate University policies, and the contracting party is unwilling to negotiate preferred changes, OSP will work with the Principal Investigator (PI) of the project to determine the PI's and/or department chair's willingness to accept the terms as written.

Examples of terms that may qualify as Nonstandard are: confidentiality, proprietary information, publication delays, licensing or ownership terms related to intellectual property, special reporting and reperformance.

Once the OSP staff member identifies an area of concern in a contract and concludes that further negotiation will not change the non-standard term(s), he/she will contact the PI, department chair or other stakeholder to get his/her approval to accept the altered terms. The standard practice is for OSP to then send a form letter to the PI (typically by email). The PI prints, signs, and returns the letter to OSP.

If the non-standard term creates a financial risk that may impact the School or College, the memo will also require the signature of the Dean's Office and an acknowledgment of acceptance of the financial risk.

The purpose of the memo is to allow the University to accept the agreement with the full understanding of all parties that the non-standard terms are less favorable to the University and investigators than terms contained in similar agreements and/or the potential financial risk will be covered by the School/Department should it occur. In certain circumstances, requirements will be included that will alleviate or reduce the legal/financial risk.

Examples of issues that require a memo are: The sponsor is granted an exclusive royalty-free license, or is assigned the intellectual property rights in situations where there is a potential for intellectual property. (Please note that OSP now accepts these terms without processing a memo when the contract is for a multi-site, sponsor-initiated clinical trial or service agreement)

- The agreement requires a present tense ("hereby assigns") assignment of intellectual property to a clinical trial sponsor.
- The agreement requires the University to absorb all patent costs.
- The agreement grants the sponsor a non-exclusive royalty-free license with the right to sublicense to third parties.
- The agreement requires that all information provided by the Sponsor, regardless of markings or delivery (oral, in writing, etc.), is confidential.
- The agreement contains any publication terms for which an exception to policy must be sought.
- The agreement requires reperformance if sponsor not satisfied with results.
- The sponsor is under a corporate integrity agreement which requires flow down of terms to VCU in the sponsored agreement.

Non-standard Terms in Material Transfer Agreements

Material Transfer Agreements often contain unique terms based on existing ownership rights to the materials. Reasonable terms are agreed to after consultation with the investigator(s) and review of the terms contained in any other sponsored research that may be related. Non-standard terms memos are required less frequently.

Technology Control Plan vs. Non-standard Terms Memo

Some restrictions on contracts involve constraints on publication or participation of foreign nationals. These terms reach a higher level of concern and may require a Technology Control Plan (TCP). TCPs are prepared by the Director, Export Compliance, in conjunction with the PI and Department. Final approval of a Technology Control Plan rests with the Vice President for Research and Innovation or designee.

Susan Robb, CRA, CHRC Date
Senior Associate Vice President
for Research Administration and Compliance