

Research Administration and Compliance Meeting  
May 25, 2011  
1:00 – 3:00 p.m.  
Larrick Hall

**Agenda**

Welcome

Staff Updates and Introductions

General Items/Updates

- FACR Revenue Distribution – Patricia Perkins
- Research Dashboard Project – Patricia Perkins
- Required Training – Investigator and Administrator Training
  - Submitted to CAR Training Subcommittee for Review
- CAR Policies and Procedures Subcommittee – Susan Robb
- G&C/OSP Relocation – Susan Robb & Mark Roberts

G&C Updates – Mark Roberts

Effort Reporting Updates – Presepine Fleming

OSP Updates

- IAF Change – Clarifications – Susan Robb
- Transaction Routing Form – Susan Robb
- NIH Deadlines – Susan Robb
- VCUeRA Workflow Update – Annie Publow
- Summer CleanUp Project – Annie Publow
- Certification Program – Annie Publow
- Clinical Trial Definition – Melanie Wiggins



# **VCU Research Dashboard Project**

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**RACM Meeting – May 25, 2011**  
**Research Administrator Update**

Tricia L. Zeh, M.S., Director of Research Administration  
Virginia Commonwealth University, School of Medicine



# What is a Dashboard?

- A customizable user interface that integrates and organizes information from multiple sources in a way that is easy to read and interpret.
- Dashboards must be built so that data is presented both accurately and timely, and with appropriate user-level security.



# What is the purpose of the VCU Research Dashboard Project?

- Develop a Research Dashboard that is:
  - Secure
  - Accurate
  - Easy-to-use
  - Customizable
- The Research Dashboard will provide:
  - Integrated access to research financial and administrative data from multiple VCU systems
  - Improved resource management, compliance, reporting, and financial management

## Dashboard Purpose cont'd...

- **Primary Audience : Principal Investigators (PI)**
- The Research Dashboard will provide PIs a central portal for managing research projects including:
  - Direct access to financial reports and management tools for their sponsored research projects
  - Administrative information such as: pending proposals, IRB/IACUC protocols, and effort commitments
  - Links to resources and training to aid in sponsored projects management.

# Dashboard Purpose cont'd

## **Secondary Audience: Dept Administration - Research Administrators, FAs, Chairs**

- The Research Dashboard will aid administrators in assisting PIs/Department Chairs in managing research portfolios by:
  - Integrating information from multiple sources into the Dashboard
  - Providing new financial management tools and improved reporting to increase efficiency and compliance in managing research projects.



# What are our goals?

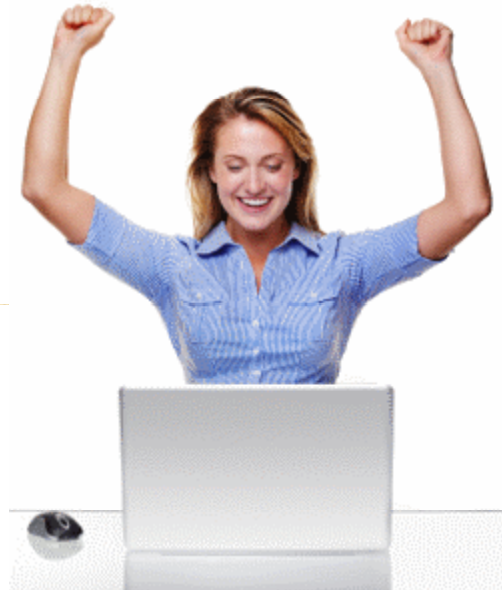
- Clear & easy-to-access information for Pls
- New and improved management tools for administrators
- Increased compliance, efficiency
- Enable better communication between Pls and administrators

# Less of This...





# More of This...



# What will the VCU Research Dashboard Include?

## Items Planned for Principal Investigators:

Management Tools:	Reports:
Active Award Direct Cost Summaries – with drill-down	Monthly Expense Reports
Personnel Commitment Checks	Payroll Distribution Reports by Effort Period
Active IRB/IACUC Protocol List	Research Portfolio Summary
Pending Proposal List	Active Award Details
Statistics	Active/Pending Support

Dashboard will include Alerts/Notifications and Links to relevant school/university resources and systems.



# Additional Features for Administration

- Department, School, VP level reports, summaries & statistical information as appropriate for each level
- Direct dashboard views in critical areas to be managed such as:
  - Research fund deficits
  - 90-day notice for personnel re-assignment
  - Effort reporting reminders/past due notices



# Current Project Status

- Detailed project specification/requirements for each user type have been defined.
- Prototypes have been developed for user groups.
- University offices working to ensure system infrastructure is laid out properly and all data needed for Dashboard is fed into ODS:
  - Office of Research
  - Controller's Office
  - Human Resources
  - Technology Services
- Updated project timeline and roll-out schedule coming soon



# Preview the Dashboard

- Principal Investigator View
- 
- Department Administration View(s)

# Questions?

t h i n k i n g





Virginia Commonwealth University  
Office of Sponsored Programs

Internal Approval Form

For OSP Office Use Only

Date & Time: \_\_\_\_\_  
OSP# \_\_\_\_\_  
Copy Received: Yes ☐ No ☐  
COI Form: Yes ☐ No ☐  
Reviewer: \_\_\_\_\_

PRINCIPAL INVESTIGATOR INFORMATION

Principal Investigator \_\_\_\_\_ (PI Name as it exists in HRS)  
Last Name First Name MI

E-mail: \_\_\_\_\_ PI Phone # \_\_\_\_\_ PI Fax # \_\_\_\_\_

PO Box \_\_\_\_\_ Department \_\_\_\_\_

Note: This department will receive credit for the award unless alternate department is listed below.

FA Name \_\_\_\_\_ FA E-mail \_\_\_\_\_ FA Phone # \_\_\_\_\_

Contact for Proposal Pickup \_\_\_\_\_ Contact E-mail \_\_\_\_\_ Contact Phone # \_\_\_\_\_

Is the department listed above also managing the project's fiscal responsibilities? Yes: ☐ No: ☐ If no, please list the department responsible for fiscal management which will receive credit for award.

Dept. for Fiscal Administration \_\_\_\_\_ FA Name \_\_\_\_\_

Fiscal FA E-mail \_\_\_\_\_ FA Phone # \_\_\_\_\_

Study Coordinator Name \_\_\_\_\_ E-mail \_\_\_\_\_

Study Coordinator Phone # \_\_\_\_\_ Fax # \_\_\_\_\_

Distribution List – Indicate email addresses to distribute documentation related to this proposal:

SPONSOR/AGENCY INFORMATION

Sponsor Name \_\_\_\_\_

Contact Name \_\_\_\_\_

Phone # \_\_\_\_\_ E-mail: \_\_\_\_\_

No Acronyms

Due Date: \_\_\_\_\_  
Receipt Date ☐ Postmark ☐  
E-Submission\* ☐

Research ☐ Clinical Trial ☐ Fellowship ☐ Training ☐ Other ☐

Does the project involve Federal Funds? Yes: ☐ No: ☐ \_\_\_\_\_  
(Originating sponsor, if applicable)

Solicitation/RFA/RFP/Award Number: \_\_\_\_\_

\*For proposals requiring Electronic Submission, the complete proposal needs to be in the OSP office no later than FIVE days before the due date.

PROPOSAL INFORMATION

Proposal Title: \_\_\_\_\_ No Acronyms

☐ New ☐ Preproposal ☐ Competing Renewal of OSP# \_\_\_\_\_ ☐ Continuation of OSP# \_\_\_\_\_  
☐ Task Order of OSP# \_\_\_\_\_ ☐ Revision of OSP# \_\_\_\_\_ ☐ Supplement of OSP# \_\_\_\_\_

Project Period	Begin:	End:
Budget Period	Begin:	End:

F&A Rate:	%
Nature:	CR <input type="checkbox"/> TFP <input type="checkbox"/> FUP <input type="checkbox"/>

Budget Information

	Year One	Year Two	Year Three	Year Four	Year Five	Project Total
Direct	\$0	0	0	0	0	\$0
Indirect	\$0	0	0	0	0	\$0
Subtotal Sponsor	\$0	0	0	0	0	\$0
Cost Share *	\$0	0	0	0	0	\$0
Total	\$0	0	0	0	0	\$0

\*For Proposals with Cost Sharing, complete the Cost Share form at <http://www.vcu.edu/finance/costsharingauthorization.pdf>

\*For Industry-Sponsored agreements, cost sharing of Principal Investigator's salary is not permitted without the approval of the V.P. for Research.

OSP Mar. 2011



PI: \_\_\_\_\_ Title: \_\_\_\_\_ Sponsor: \_\_\_\_\_

Is this project being conducted through a Chartered Center or Institute? Yes: ☐ No: ☐

If "YES", please indicate the Center or Institute: \_\_\_\_\_

(The list of Chartered Centers and Institutes is available at [www.research.vcu.edu/vpr/institutes.htm](http://www.research.vcu.edu/vpr/institutes.htm))

The proposed project will use the services of the following Service Areas or Core Facility\*(attach a copy of approved pricing sheet from each area):

- ☐ Respiratory Care    ☐ Radiology    ☐ CCTR    ☐ MCV Physicians    ☐ Pathology  
☐ In-Patient Beds    ☐ Nursing Support    ☐ Pulmonary/Bronchoscopy    ☐ Investigational Pharmacy    ☐ Clinical Trials Office  
☐ Health Information/Computing    ☐ Survey Evaluation Research Lab    ☐ Biostatistics    ☐ Other: \_\_\_\_\_

☐ Core: \_\_\_\_\_

\* Core facility listing can be found at [www.research.vcu.edu/vpr/core\\_laboratory.htm](http://www.research.vcu.edu/vpr/core_laboratory.htm)

## PERCENT EFFORT AND PERCENT RESPONSIBILITY ON PROJECT

### Key Personnel and Faculty:

Key	Name	Role on Project	CAL Mnths	ACAD Mnths	SUMR Mnths	% EFFORT	% RESP	COI Form	
<input type="checkbox"/>								Signed <input type="checkbox"/>	Sal Esc <input type="checkbox"/>
<input type="checkbox"/>								Signed <input type="checkbox"/>	Sal Esc <input type="checkbox"/>
<input type="checkbox"/>								Signed <input type="checkbox"/>	Sal Esc <input type="checkbox"/>
<input type="checkbox"/>								Signed <input type="checkbox"/>	Sal Esc <input type="checkbox"/>
<input type="checkbox"/>								Signed <input type="checkbox"/>	Sal Esc <input type="checkbox"/>

\*Please use the Continuation Page for additional Co PI listings (<http://www.research.vcu.edu/forms/ContinuationPageNov2010.doc>)

## COMPLIANCE DATA

-If project is research or clinical trial, please indicate:

Basic ☐ Applied ☐ Developmental ☐

The proposal enclosed involves the following:

Yes	No	Maybe		Yes	No		Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>		Human Subjects Research <sup>1</sup> (If yes, complete table below)	<input type="checkbox"/>	<input type="checkbox"/>	Radioactive Materials <sup>4,5</sup>	<input type="checkbox"/>	<input type="checkbox"/>	Clinical Trial
<input type="checkbox"/>	<input type="checkbox"/>		Animal Use <sup>2</sup> (If yes, complete table below)	<input type="checkbox"/>	<input type="checkbox"/>	Recombinant DNA, Select Agents or other biohazards <sup>4,5</sup>	<input type="checkbox"/>	<input type="checkbox"/>	Research is subject to export controls
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Foreign Nationals	<input type="checkbox"/>	<input type="checkbox"/>	Company Confidential Information will be provided	<input type="checkbox"/>	<input type="checkbox"/>	Sponsor is foreign- owned company or foreign government
<input type="checkbox"/>	<input type="checkbox"/>		Restrictions on Publication or Intellectual Property Rights	<input type="checkbox"/>	<input type="checkbox"/>	International Program	<input type="checkbox"/>	<input type="checkbox"/>	Program Income
<input type="checkbox"/>	<input type="checkbox"/>		Retired faculty participation	<input type="checkbox"/>	<input type="checkbox"/>	Subcontracts or subrecipients <sup>6</sup> (external)	<input type="checkbox"/>	<input type="checkbox"/>	Wet lab space
<input type="checkbox"/>	<input type="checkbox"/>		Rented off campus facility	<input type="checkbox"/>	<input type="checkbox"/>	Subaccounts (internal) <sup>6</sup>	<input type="checkbox"/>	<input type="checkbox"/>	Additional/New space
<input type="checkbox"/>	<input type="checkbox"/>		Delivery of anything more than technical report	<input type="checkbox"/>	<input type="checkbox"/>	NSF Funds- RCR Training Required	<input type="checkbox"/>	<input type="checkbox"/>	NIH Funds- RCR Training Required
<input type="checkbox"/>	<input type="checkbox"/>		HIPAA Covered Data <sup>3</sup>						

1. For further information on human subjects research refer to: <http://www.research.vcu.edu/irb/activities.htm>

2. For further information on animal research refer to: <http://www.research.vcu.edu/iacuc/index.htm>

3. Contact contact VCUHS Compliance Services at <http://www.vcuhealth.org/?id=865&sid=1> or 828-0500

4. For more information on environmental health requirements refer to <http://www.vcu.edu/oehs/>

5. For more information on chemical and biosafety requirements refer to <http://www.vcu.edu/oehs/chemical/biosafe/IBChome.pdf>

6. If Yes, complete Internal Approval Form Proposal Budget Detail, <http://www.research.vcu.edu/forms/IAFProposalBudgetDetail.xls>

**PROTOCOLS:** Principal Investigator / Co PI(s)

IRB/IACUC No.

Approval Date






PI: \_\_\_\_\_ Title: \_\_\_\_\_ Sponsor: \_\_\_\_\_

## PRINCIPAL INVESTIGATOR CERTIFICATIONS, DISCLOSURES AND ASSURANCES

By signing below I certify that I have read and understand the statements below and those contained in this *Internal Approval Form* and further certify that the statements contained herein are accurate and truthful to the best of my knowledge and belief:

- | Yes                      | No                       |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | All applicable items contained in the <b>Compliance Data</b> section have been identified. Investigator agrees to abide by any obligations applicable under VCU policies or other legal requirements (e.g., obtaining protocol approvals, adhering to export control laws, maintaining confidentiality, etc.).  |
| <input type="checkbox"/> | <input type="checkbox"/> | Investigator has read and understands VCU's Conflict of Interest and Researcher Financial Conflict of Interest policies, has made any required disclosures, and prior to the expenditure of any awarded funds, if applicable, shall have reached an agreement with VCU for conditions or restrictions to reduce, manage or eliminate any conflicts of interest under University policy.   |
| <input type="checkbox"/> | <input type="checkbox"/> | The enclosed proposal is complete in technical content, adheres to norms of proper scholarship and responsible conduct of research, including proper citation and attribution for all text and graphics, complies with federal guidance on research integrity (e.g., see VCU policy on responsible conduct in research), and is in accordance with all specifications from the sponsoring agency.   |
| <input type="checkbox"/> | <input type="checkbox"/> | The space/facilities and other VCU resources necessary to conduct the proposed project are currently available to the investigators and if not currently available, arrangements will be made with the Department/School/Division to make all necessary resources available in the event an award is made by the sponsor.   |
| <input type="checkbox"/> | <input type="checkbox"/> | If the proposal enclosed is funded and accepted by VCU, Investigator agrees to conduct the project in accordance with all terms and conditions stipulated by the sponsoring agency and all applicable VCU policies and procedures; furthermore, Investigator agrees to be fully responsible in meeting the requirements of the award, including but not limited to, proper and ethical stewardship of funds, timely submission of all required technical reports and deliverables, proper disclosure of all inventions to VCU's Technology Transfer Office, and also adhering to all federal compliance requirements (e.g., Export Control, HIPAA, IRB, IACUC, other Human Research protections, etc.). |
| <input type="checkbox"/> | <input type="checkbox"/> | Investigator acknowledges that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.  |

**PI Signature**

**Date**

\*The Conflict of Interest Disclosure form is available at <http://www.research.vcu.edu/forms/ConflictofInterestDisclosureForm.doc>.

## REQUIRED SIGNATURES

We, the undersigned, do certify to the best of our knowledge and behalf that 1) the designated faculty will be released for the effort indicated; 2) personnel costs are correctly estimated; 3) adequate and suitable space is/will be provided for completion of the project; 4) no named participant is debarred from this application; and 5) this project is consistent with the educational and research objectives of the University. If applicable, signature of the Dean verifies that all joint VCU/VA appointees have a current Memo of Understanding (MOU) on file in their Dean's office. For additional signature areas, please see the Continuation Page (<http://www.research.vcu.edu/forms/ContinuationPageNov2010.doc>).

_____ Principal Investigator/Date	<input type="checkbox"/>	A copy of this proposal has been delivered to my Department Chair for review. (Check Box)	_____ Dean/Date
_____ Co-Investigator/Date	<input type="checkbox"/>	A copy of this proposal has been delivered to my Department Chair for review. (Check Box)	_____ Dean/Date
_____ Co-Investigator/Date	<input type="checkbox"/>	A copy of this proposal has been delivered to my Department Chair for review. (Check Box)	_____ Dean/Date
_____ Services Investigator/Date	<div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> <b>Appropriate approvals obtained (see above). Approved on behalf of the University:</b> </div>		_____ Dean/Date
_____ Clinical Trials Office/Date* (*Only if Clinical Trial)	<div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;">         University Official/Date       </div>		

## Clarification of NIH Fiscal Policy for Grant Awards – FY 2011

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**Notice Number:** **NOT-OD-11-077**

### Key Dates

Release Date: May 20, 2011

### Related Notice

[NOT-OD-11-068](#)

### Issued by

National Institutes of Health (NIH), (<http://www.nih.gov>)

This Notice provides clarification to the guidance about the NIH Fiscal Operations Plan for FY 2011 and implementation of the Department of Defense and Full-Year Continuing Appropriations Act of 2011 (P.L. 112-10) that was announced in [NOT-OD-11-068](#).

**Non-Competing Research Awards for All NIH Institutes and Centers (ICs) Except the National Cancer Institute (NCI):** The FY 2011 appropriation level specified in P.L. 112-10 reduces funding from FY 2010 levels and thus warrants reductions in commitment levels for NIH research grants. Non-modular research grants, from all ICs, with the single exception of NCI, will be reduced to 1 percent below the FY 2010 award level. Future year commitments will be adjusted for inflation based on this revised FY 2011 level, taking into account the policy assumption in the FY 2012 President's Budget. Modular grants will be reduced to 1 percent below the FY 2010 level and may be reduced by an inflationary adjustment level set by each Institute or Center (up to the level set by that Institute or Center for non-modular research grants). The adjusted FY2011 award level will also be the new base for future year commitments.

**Non-Competing Research Awards for NCI:** For NCI, Non-modular research grants will be reduced to 3 percent below the FY 2010 award level. Future year commitments will be adjusted for inflation based on this revised FY 2011 level, taking into account the policy assumption in the FY 2012 President's Budget. Modular grants will be reduced to 3 percent below the FY 2010 level.

**Additional Information:** Additional details on Fiscal Operations, including specific funding strategies for ICs will be posted at <http://grants.nih.gov/grants/financial/index.htm>.

### Inquiries

Questions about specific awards may be directed to the Grants Management Specialist identified in the Notice of Award.

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[Weekly TOC for this Announcement](#)  
[NIH Funding Opportunities and Notices](#)

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	National Institutes of Health (NIH)	Department of Health
Office of		



Extramural  
Research  
(OER)



9000  
Rockville  
Pike  
Bethesda,  
Maryland  
20892



and Human  
Services  
(HHS)



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**Note:** For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](#).

VCU  
Office of Sponsored Programs  
Office of Research



Committee on the Administration of Research's  
Research Administration and Compliance Meeting  
OSP VCUeRA Workflow and Closeout Update  
Annie Publow, Director of Sponsored Programs,  
Government/NonProfit Support  
May 25, 2011

# VCUeRA Workflow and Closeout Update

## Presentation Topics:

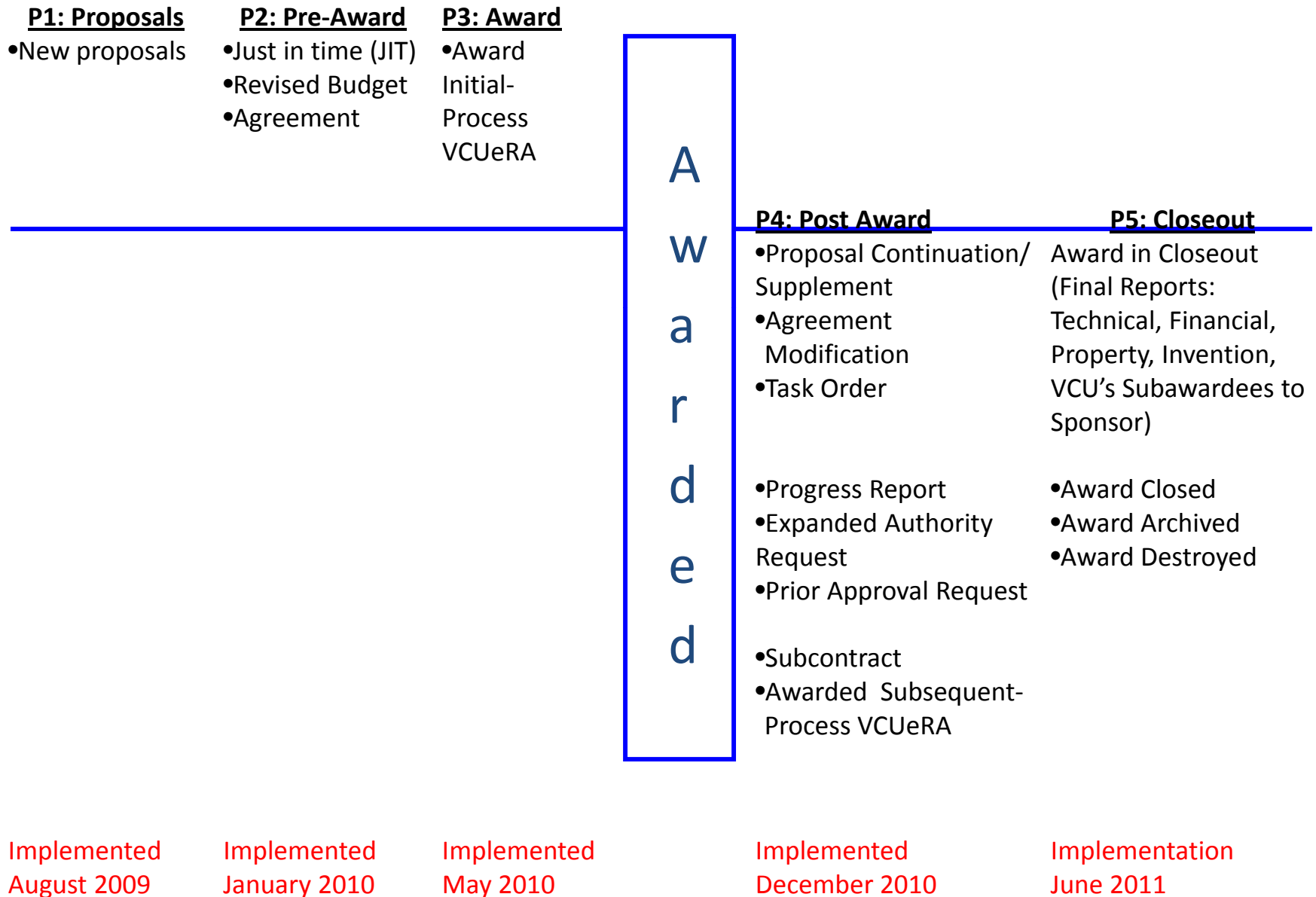
- VCUeRA Workflow
  - Progress to date
  - Phase Four, the “Post Award” Transactions Implemented
  - Updated Phase Five Diagram and Definitions
  - Notifications: What you Need to Know
    - Associated emails
    - “Status” versus Activity Table: location and use
- Closeout of Older Awards and “Not Awarded” Proposals
- Sponsored Project Administration Certification Program

# Progress to Date

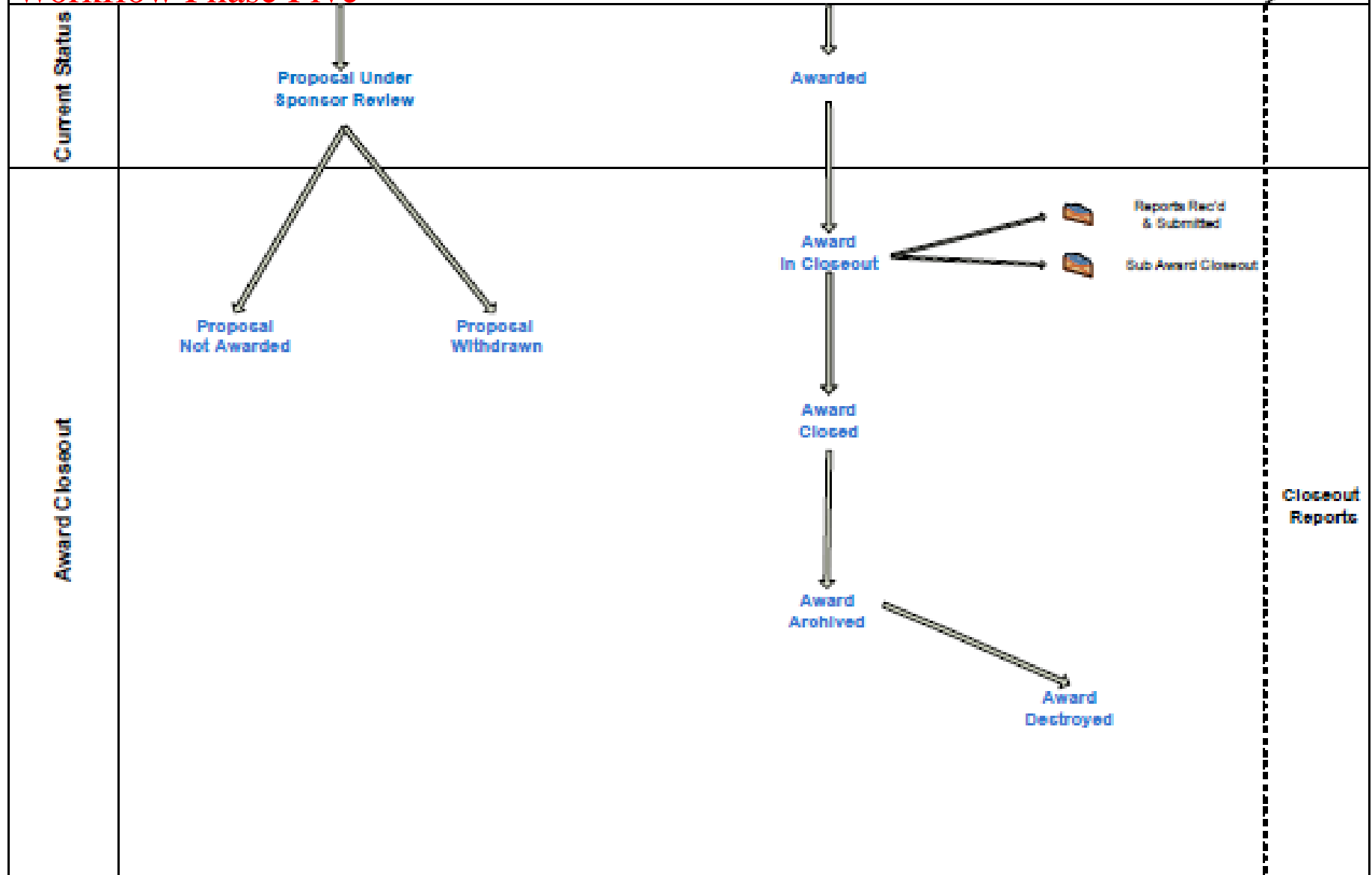
## Why Workflow?

- Consistency across OSP teams and reviewers
- Efficiency of process
- Transparency of procedures
- Report current status
- Clarification of OSP roles and responsibilities
- Documentation of compliance
- Focus on OSP internal “hand offs”

# VCU OSP Sponsored Project Workflow Phases



## Workflow Phase Five





## VCU OSP Sponsored Project Workflow Phase Five Definitions

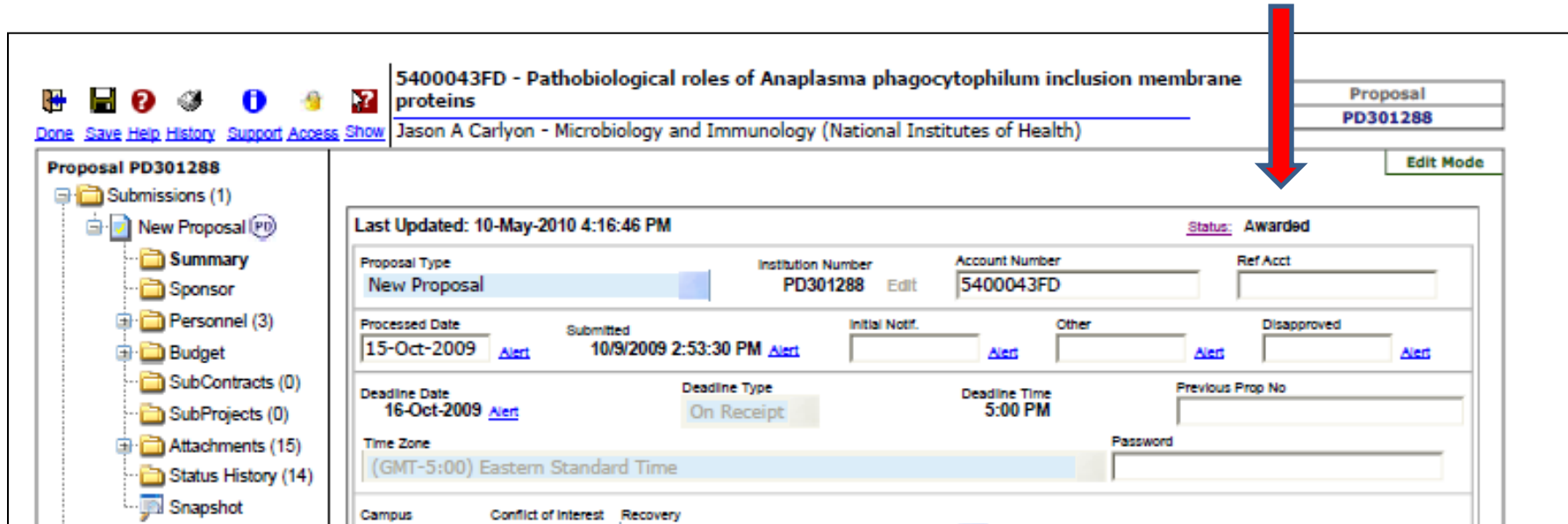
Status	Definition	Descriptor
<b>Award in Closeout</b>	The award is complete and all required final reports are due. OSP is in the process of documenting final report submission and closing the award.	Will identify the records with expired performance periods. We'll assess what's needed by the sponsor to close out the record.
<b>Award Closed</b>	The award is complete, all final reports have been submitted. OSP has closed the award.	Identify what we need to do for OSP to physically close out the record which includes scanning the complete hard copy record and saving to locked down storage.
<b>Award Archived</b>	The award is closed and the file has been moved to archival storage.	All steps completed for sponsor and OSP and physical record can be destroyed. This is our new "terminus"- or final step
<b>Award Destroyed</b>	Archival requirements have expired. The archived documents have been destroyed.	A historical status we need to retain for those records we retained for the required 5 years, sought permission to physically destroy and, which we do not retain any record of in either physical or electronic form.

# Closeout Notifications: What you Need to Know

- Developing emails notifications to support the Closeout process-will have same “look and feel” of other VCUeRA communications
- Developing the reports to help with tracking of awards in closeout
- Internally, OSP will utilize both the “status” as well as the “Activity Table” features to track records being closed out

# Status Inquiries:

## First Check VCUeRA PT/PD record



The screenshot displays the VCUeRA PT/PD record for Proposal PD301288. The interface includes a top navigation bar with icons and a menu (Done, Save, Help, History, Support, Access, Show). The main header shows the proposal title: "5400043FD - Pathobiological roles of Anaplasma phagocytophilum inclusion membrane proteins" and the investigator: "Jason A Carlyon - Microbiology and Immunology (National Institutes of Health)".

On the left, a sidebar lists the proposal components: Submissions (1), New Proposal (PD), Summary, Sponsor, Personnel (3), Budget, SubContracts (0), SubProjects (0), Attachments (15), Status History (14), and Snapshot.

The main content area displays the following information:

- Last Updated:** 10-May-2010 4:16:46 PM
- Status:** Awarded
- Proposal Type:** New Proposal
- Institution Number:** PD301288
- Account Number:** 5400043FD
- Ref Acct:**
- Processed Date:** 15-Oct-2009
- Submitted:** 10/9/2009 2:53:30 PM
- Initial Notif.:**
- Other:**
- Disapproved:**
- Deadline Date:** 16-Oct-2009
- Deadline Type:** On Receipt
- Deadline Time:** 5:00 PM
- Previous Prop No:**
- Time Zone:** (GMT-5:00) Eastern Standard Time
- Password:**
- Campus:**
- Conflict of Interest:**
- Recovery:**

A red arrow points to the "Proposal PD301288" label in the top right corner of the form.

# VCUeRA Summary Screen

**5400043FD - Pathobiological roles of Anaplasma phagocytophilum inclusion membrane proteins**  
 Jason A Carlyon - Microbiology and Immunology (National Institutes of Health)

Proposal  
**PD301288**  
 Edit Mode

**Proposal PD301288**  
 Submissions (1)  
 New Proposal (P)  
 Summary  
 Sponsor  
 Personnel (3)  
 Budget  
 SubContracts (0)

Last Updated: 19-Jan-2011 12:10:44 PM  
 Status: **Awarded**  
 Proposal Type: **New Proposal** Institution Number: **PD301288** Account Number: **5400043FD** Ref Acct:  
 Processed Date: **15-Oct-2009** Submitted: **10/9/2009 2:53:30 PM** Initial Notif.: Other: Disapproved:  
 Deadline Date: Deadline Type: Deadline Time: Previous Prop No:

**DO NOT USE - Activity Intake Date / Time - DO NOT USE**

Activity Table (Add)

Activity	Date Received to OSP	Hour Received	Minute Received	AM / PM	Deadline Date or Date to Post Award	Submitted Date or Distribution Date	Returned Date		
P2 - JIT Requested	23-Apr-2010	09	10	AM	30-Apr-2010			Edit	
P1 / P4 - Proposal Received	25-Oct-2009	10	52	AM	16-Oct-2009	09-Oct-2009	09-Oct-2009	Edit	
P3 / P4 - Award Received	07-May-2010					07-May-2010		Edit	

Current Activity Table

Current - Activity Table (Add)

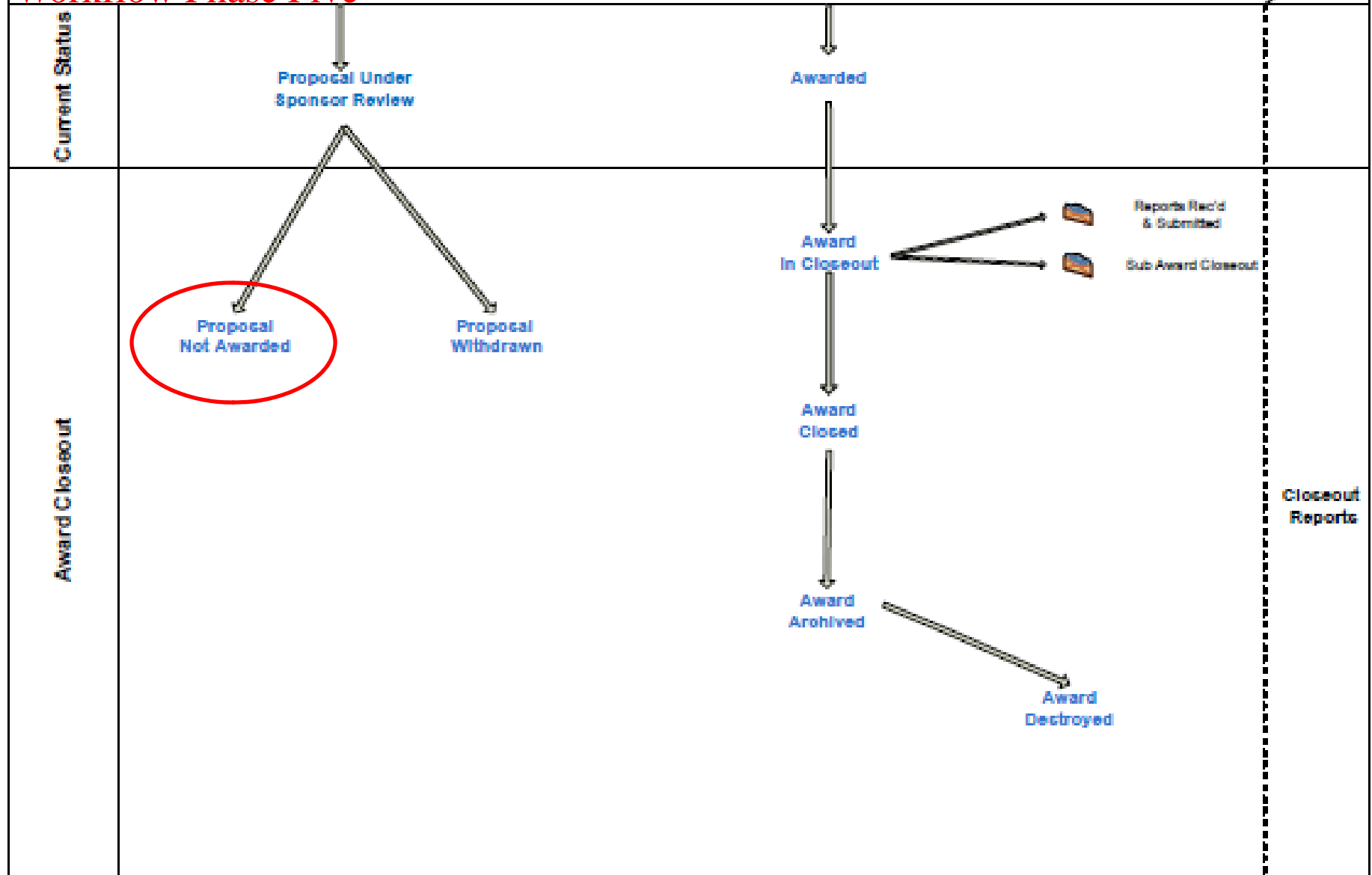
Activity	Date Received to OSP (P1,P3) , Awarded New Action Received (P4) , Project End Date (P5)	Hour Recd	Minute Recd	AM / PM	Deadline Date, Date to Post Award (P3, P4)	Responsible Individual	Descriptor (P4, P5)	Awarded New Action Review (P4, P5)	Awarded New Action Needs Response (P4, P5)	Submitted (P1), Processed (P2), Distributed (P3), Awarded New Action Completed (P4), Closed (P5)	Returned Date (P1)	Comments (P4, P5)		
P3 - Award Received	07-May-2010									07-May-2010			Edit	
P1 - Proposal Received	25-Oct-2009	10	52	AM	16-Oct-2009					09-Oct-2009	09-Oct-2009		Edit	
P2 - JIT Requested	23-Apr-2010	09	10	AM	30-Apr-2010					07-May-2010			Edit	

Activity  
Table

# Summer Closeout Project

- Closeout needed for ~1200 records: Awards that have ended.
- In many cases, whatever was due to the sponsor has been submitted and what remains to be done is only internal, however we will be assessing each record (and contacting PI/FA as needed) to ensure we're thorough in our process. We'll contact PI/FA if items are missing.
- OSP Post Award Team coordinates closeout for Government/NonProfit records: [ospaward@vcu.edu](mailto:ospaward@vcu.edu)  
Amy Lutero, Post Award Manager

## Workflow Phase Five



# Summer Closeout Project

## Update on “Not Awarded” Records:

- Have been utilizing NIH’s eraCommons to identify proposals that were triaged (so we can remove them from our active records)
- Have sought update from CAR (Committee on Administration of Research) school members for oldest of the records-OSP currently processing those responses
- Our plan to initiate regular emails directly to Principal Investigators a year from submission to query status

# Sponsored Project Administration Certification Program

- Program runs annually from September-December, 2011
- 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



# Sponsored Project Administration Certification Program

## Course Outline:

Each module consists of on-line material and one live lecture with subject review and case studies. Each module is divided into units. A quiz follows each unit and an on-line exam follows each module.

### ***Module 1: Pre-Award to include:***

Overview, proposal preparation, budget building basics, advanced budget/proposal preparation

### ***Module 2: Compliance to include:***

Research protections, research security, administration (OMB Circular A-110), intellectual property, research integrity

### ***Module 3: Clinical Trials to include:***

Clinical trials overview, budgeting for clinical trials, master agreements, WIRB, study termination and closeout

### ***Module 4: Post Award Basics to include:***

Costing (OMB Circular A-21), accounting, personnel, purchasing, account management

### ***Module 5: Project Management to include:***

Advanced project management, Recordkeeping and Audit, other Special Situations

What is the Definition of a Clinical Trial at  
VCU?  
And Why Is the Definition Important?

Melanie Wiggins  
Director, OSP-Industry

# VCU's Definition of a Clinical Trial

**Clinical Trial:** A clinical trial is an **interventional or observational prospective research study** involving **human subjects** that is designed to answer specific questions about biomedical (e.g., drugs, treatments, devices) or behavioral **interventions** (e.g., diet modifications, physical activity) through the compliant **collection and analysis of safety and efficacy data as measurement for health outcomes**. In an interventional clinical trial, research subjects are assigned to a treatment or other intervention and their outcomes are measured. In an observational clinical trial, interventions given during the course of clinical care are observed and outcomes are measured by the researchers. Preclinical laboratory studies or studies in animals are not considered clinical trials.

# Clinical Research vs Clinical Trial

A clinical trial is considered clinical research but not all clinical research is considered to be a clinical trial.

# Examples of Clinical Research

Human subjects research describing:

- The mechanism of human disease (diagnosing Alzheimers Disease)
- The use of therapies or interventions for disease.
- Patient registries (tracking long term survival rate of liver transplant patients)
- Data collection studies (e.g., blood samples and information on symptoms of pancreatitis)

# Examples of Clinical Trials

Human subject research involving:

- Evaluations of new drugs, devices or treatments.
- Evaluations of existing drugs or devices for a new use.
- Prevention studies such as vaccine
- Post marketing studies involving an approved therapy and looking at treatment success, adverse reactions, etc.
- Behavioral studies modifying lifestyle such as diet or physical activity and the associated affects on health.

# Where do I find the Definition of a Clinical Trial?

InternalApprovalForm (Read-Only) [Compatibility Mode] - Microsoft Word 2007

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Virginia Commonwealth University  
Office of Sponsored Programs  
Internal Approval Form

For OSP Office Use Only  
Date & Time: \_\_\_\_\_  
OSP: \_\_\_\_\_  
Copy Received: Yes ☐ No ☐  
COI Form: Yes ☐ No ☐  
Reviewer: \_\_\_\_\_

**PRINCIPAL INVESTIGATOR INFORMATION**

Principal Investigator \_\_\_\_\_ (PI Name as it exists in HRS)  
Last Name First Name MI  
E-mail: \_\_\_\_\_ PI Phone # \_\_\_\_\_ PI Fax # \_\_\_\_\_  
PO Box \_\_\_\_\_ Department \_\_\_\_\_  
Note: This department will receive credit for the award unless alternate department is listed below.  
FA Name \_\_\_\_\_ FA E-mail \_\_\_\_\_ FA Phone # \_\_\_\_\_  
Contact for Proposal Pickup \_\_\_\_\_ Contact E-mail \_\_\_\_\_ Contact Phone # \_\_\_\_\_  
Is the department listed above also managing the project's fiscal responsibilities? Yes: ☐ No: ☐ If no, please list the department responsible for fiscal management which will receive credit for award.  
Dept. for Fiscal Administration \_\_\_\_\_ FA Name \_\_\_\_\_  
Fiscal FA E-mail \_\_\_\_\_ FA Phone # \_\_\_\_\_  
Study Coordinator Name \_\_\_\_\_ E-mail \_\_\_\_\_  
Study Coordinator Phone # \_\_\_\_\_ Fax # \_\_\_\_\_  
Distribution List - Indicate email addresses to distribute documentation related to this proposal:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**SPONSOR/AGENCY INFORMATION**

Sponsor Name \_\_\_\_\_ No Acronyms \_\_\_\_\_  
Contact Name \_\_\_\_\_ Due Date: \_\_\_\_\_  
Phone # \_\_\_\_\_ E-mail: \_\_\_\_\_ Receipt Date ☐ Postmark ☐  
E-Submission\* ☐  
Research ☐ Clinical Trial ☐ Fellowship ☐ Training ☐ Other ☐  
\*See last page for key definition

Words: 0

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# Where do I find the Definition of a Clinical Trial

**The definition of a clinical trial can be found:**

(1) On the Internal Approval Form

<http://www.research.vcu.edu/forms/osp.htm>

(2) Under the OSP Index

<http://www.research.vcu.edu/osp/glossary.htm#ClinicalTrial>

(3) On the Clinical Trial Office Website

<http://www.cto.vcu.edu/about/index.html>

AND

(4) In the Policy on Corporate Sponsored Research

[http://www.research.vcu.edu/p\\_and\\_g/corpagreement.htm](http://www.research.vcu.edu/p_and_g/corpagreement.htm)



# Why is the Definition Important?

- Both the Clinical Trials Office (CTO) and the Office of Sponsored Programs (OSP) track clinical trials.
- The CTO tracks all clinical trials conducted at VCU for inclusion in their database as part of their mission to support and grow clinical research under the Center for Clinical and Translational Research .

<http://www.clinicaltrials.vcu.edu/search.html>

# Why is the Definition Important?

- OSP tracks clinical trials in the VCUeRA database for award reporting purposes.
- VCU applies a special facilities and administrative (F&A) rate of 25% of total direct costs for industry and other non-federal sponsors.
- VCU tracks registration of clinical trials to [clinicaltrials.gov](https://clinicaltrials.gov) in compliance with VCU policy and federal law.

# Contact Information for Questions

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