Research Administration and Compliance Meeting
September 15, 2010
Agenda

Welcome

General Items/Updates

- Research Administration Roles and Responsibilities Matrix – Susan Robb
- Post-Award Administration Compliance – Fiscal Responsibilities – Tricia Perkins

G&C Updates

- ECRT Training Update – Presepine Fleming
- NIH Expanded Authorities/SNAP-Eligible Grant Accounting – Mark Roberts

Clinical Trial Office Update – Tammy Anderson

- New Website
- CTO Review of Clinical Trial Paperwork

OSP Updates

- OSP Statistics – FY 2010
- New Internal Approval Form – Susan Robb
- VCU Survey for NSF Survey – Susan Robb
- NCURA/EARMA Fellowship to Karolinska Institute in Sweden – Erica Lawler
- VCUeRA Workflow Update – Annie Publow
- Just-In-Time Submissions – Annie Publow and Jaime Petrasek
- Certification Program Update – Annie Publow
- Recent NIH Changes & Announcements – Susan Robb
    - Electronic SNAP Reports required 8/1/10
    - X-Train – Required 1/1/11 –Training Sessions held
    - Post-Submission Application Materials Requirements Changing – 9/25/10
    - Two-Day Correction Window eliminated – effective 1/25/11

Future RACM dates – location to be determined

- January 19, 2011 – 1:00 – 3:00 p.m.
- May 25, 2011 – 1:00 – 3:00 p.m.

VIRGINIA COMMONWEALTH UNIVERSITY
RESEARCH ADMINISTRATION - ROLES AND RESPONSIBILITIES MATRIX

RESPONSIBILITIES	PI	DEPT ADMIN	DEPT CHAIR	DEAN OFF	OSP	G&C	ORSP/ IRB/ IACUC	VP RES	VP FIN	TECH TRANS	IBC	COIC	ASSUR SVCS	Others with Roles*
KEY														
P = PRIMARY RESPONSIBILITY														
S = SECONDARY RESPONSIBILITY														
I. GENERAL RESEARCH ADMINISTRATION ACTIVITIES AND SUPPORT														
Strategic														
Direct and guide the University's research mission								P						
Develop and direct new University research centers				S				P						
Nurture technology related relationships and partnerships with industry and government.				S				P		S				
Evaluate individual workloads and staffing levels compared to sponsored program growth to determine staffing needs within Unit Admin and Central Admin			P	P	P	P								
Policy														
Participate in policy formulation					S	S	S	P	P	S	S	S		
Review, interpret and disseminate policies from federal and non-federal funding and regulatory agencies					P	P	P				P			
Keep current with policies related to compliance activities and assess and communicate their effect on the University					P	P	P				P			
Interpret and implement University policies related to grants and contracts					P	P					P			
Develop standard procedures for research processes					P	P	P				P			
Oversee Limited Submission Policy/process					P									
Training														
Develop training strategy for research community							S	P	P					ORCE (P)
Develop training curriculum					P	P								
Prepare content for individual training sessions or modules and lead training sessions					P	P	P							ORCE (P)
Monitor the delivery of the training and assess the effectiveness					P	P		S	S					ORCE (P)
Monitor compliance requirements and ensure training program is modified as necessary					P	P	P	S	S					ORCE (P)

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*See last page for identification of Others With Roles

KEY
P = PRIMARY RESPONSIBILITY
S = SECONDARY RESPONSIBILITY

Last Updated 9/14/2010

ECRT & Effort Reporting Training Update

Presepine Fleming
Effort Reporting
Virginia Commonwealth University
September 15, 2010

Effort & ECRT Training Matrix

VCU University Controller's Office
Finance and Administration

ECRT Users And/Or Department Fiscal Staff

	Certifier	Principal Investigator	Effort Coordinator	Fiscal Administrators	Grant Personnel
Instructor Led					
Effort Reporting- Basic			X		
Effort Reporting- Intermediate			X		
Compliance Training Series	X	X	X	X	X
On-line Training					
Certifying My Effort-ECRT Training Video	X	X	X		
Certifying Effort for Others-ECRT Training Video		X			
MCV Campus Faculty- Effort Reporting Primer	X	X			
MCV Campus Fiscal Administrator- Effort Reporting Primer			X	X	X
Monroe Park Campus Faculty- Effort Reporting Primer	X	X			
Monroe Park Campus Fiscal Administrator- Effort Reporting Primer			X	X	X

ECRT & Effort Reporting's Instructor Led Courses

- Beginners
  - Upcoming dates: 10-19-10 & 11-09-10
  - Topics: overview of effort reporting, ECRT navigation and reports, system upgrade, and compliance
- Intermediate
  - Upcoming dates: 09-15-10 & TBD
  - Topics: detail review of effort reporting, ECRT navigation and reports, system upgrade, and compliance
- Compliance
  - Upcoming dates: 09-22-10 & TBD
  - Topics: audio conference of federal compliance documentation & TBD

ECRT & Effort Reporting's On-Line Training

- Effort Reporting Primers
  - Used for mandatory effort training
- Faculty Recertification Training (upcoming)
  - Combined with Office of Sponsored Programs
- ECRT Help File (ECRT System)
- Effort Reporting's Website (other training resources)
  - Helpful Tools
  - FAQ
  - Other University Research Training Opportunities
  - Effort Reporting Related Links

Training Resources

- Questions?
- Contacts
  - Mark Roberts (804) 828-0033, mroberts8@vcu.edu
  - Presepine Fleming (804) 828-2056, flemingpm@vcu.edu
  - Elaine Squire (804) 828-0743, esquire@vcu.edu
  - Tricia Kelly (804) 828-5667, takelly@vcu.edu
  - Effort Reporting's email: effortreport@vcu.edu
- Links
  - Effort Training site: http://www.controller.vcu.edu/grants/ECRTtrain.html
  - Effort Reporting's Website: http://www.controller.vcu.edu/grants/effort.htm
  - ECRT: https://effort.ts.vcu.edu/ecrt/initLogin.do

September 15, 2010 Research Administration and Compliance Meeting

G&C UPDATE:

NIH Expanded Authorities/SNAP-Eligible Grant Accounting

What has changed?

- A single Banner grant fund/index number will be used for the entire duration of the competitive segment (e.g. 5 yrs. for most NIH grants), for awards with expanded authorities and SNAP provisions.

Why the change?

- G&C currently creates separate Index numbers in Banner for each year of an award for NIH. Using multiple numbers over the duration of these awards creates a significant amount of additional work with regard to setup and administration, for both G&C and campus administrators.

Why now?

- An assessment of current business processes by an external consulting firm resulted in a recommendation to VCU management, to make this change to align with best industry practices, and to enhance our ability to continue to meet the needs of the growing VCU research enterprise.

Transitioning the change

- New NIH awards will be reviewed for terms requiring Expanded Authority/SNAP provisions.
- NIH continuation awards entering budget year 2 forward, that as of today have not had new Banner index numbers created, will also be transitioned with a single number.
- When required, a single sub-account will also be used for the entire period for each sub-account.

Other Considerations....

- Project End Date on FRAGRNT will continue to reflect the NIH project period end date.
- Other dates on FTMFUND and FRMFUND will continue to be based on the current Budget Period, and will annually be updated by the G&C Accountant only upon receipt of a Notice of Award from the Office of Sponsored Programs, or upon receipt of a appropriately signed 90-Days Notice.
- Fiscal monitoring is still required by departmental administrator and P.I. as necessary for annual progress reporting.
- A new sub-category code “X” has been created on FRAGRNT to identify newly transitioned NIH Expanded Authority/SNAP awards.

Questions.....

- Contact Mark Roberts, Director of Grants and Contracts Accounting; email mroberts8@vcu.edu or call 828-0033
- Or contact your G&C Accountant

VIRGINIA COMMONWEALTH UNIVERSITY

Number of Awards by Sponsor Type and Award Type for FY2010

Starting Unit: Virginia Commonwealth University ; Reference Date: Entire Fiscal Year ; OSP Team: <all teams>

	Carryforward	Continuation	Decrease	Initial	No Cost Extension	Supplement	Valid Zero Value	Total
College/University	1	43	5	75	21	8	3	**156**
Department of Defense		2		15	5	1		**23**
Department of Education		20		9	5	4	1	**39**
Department of Energy		1		2	1	1		**5**
Department of Health & Human Services	5	16	2	10	4	2	2	**41**
Department of Justice					1			**1**
Department of Labor		1			1			**2**
Department of State				1				**1**
Federal	4	12	2	14	11	1	1	**45**
Federal Laboratory		1						**1**
Foreign Government		1		1				**2**
Foundation	1	21	3	54	19	2		**100**
Hospital		10		8	2	2		**22**
Industry		21	1	151	116	20	7	**316**
Local VA	2		2	13				**17**
National Aeronautics & Space Agency		3		2		1		**6**
National Institutes of Health	11	206	15	139	76	30	15	**492**
National Science Foundation		19		25	10	12	4	**70**
Non-Profit	2	30	4	78	35	1	1	**151**
Nuclear Regulatory Commision		1		1				**2**
Professional/Academic Assoc & Soc.	2	3	1	13	8	1		**28**
Research Organization		1		9	5		1	**16**
Social Security Administration				100	1	9	3	**113**

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	Carryforward	Continuation	Decrease	Initial	No Cost Extension	Supplement	Valid Zero Value	Total
State Non-VA		1		3				**4**
State VA	2	46	7	88	20	13	5	**181**
Total	**30**	**459**	**42**	**811**	**341**	**108**	**43**	**1834**

VIRGINIA COMMONWEALTH UNIVERSITY
SPONSORED PROGRAM AWARD STATUS

Reference Date: Entire Fiscal Year **Office: <all teams>**

	FY2010	FY2009	FY2009 Entire Fiscal Year
College/University	$6,755,649	$6,903,284	$6,903,284
Department of Defense	$3,084,485	$4,526,467	$4,526,467
Department of Education	$8,450,396	$10,666,771	$10,666,771
Department of Energy	$379,500	$362,051	$362,051
Department of Health & Human Services	$6,902,755	$6,740,194	$6,740,194
Department of Justice	$0	$100,265	$100,265
Department of Labor	$424,800	$919,685	$919,685
Department of State	$81,133		
Federal	$4,363,987	$3,968,209	$3,968,209
Federal Laboratory	$90,000	$128,600	$128,600
Foreign Government	$373,631	$371,750	$371,750
Foundation	$47,501,498	$46,390,012	$46,390,012
Hospital	$6,996,706	$8,786,302	$8,786,302
Industry	$19,949,412	$16,345,556	$16,345,556
Local VA	$446,074	$1,790,936	$1,790,936
National Aeronautics & Space Agency	$604,463	$348,587	$348,587
National Institutes of Health	$102,136,525	$84,861,543	$84,861,543
National Science Foundation	$6,887,198	$4,778,414	$4,778,414
Non-Profit	$6,960,243	$5,456,592	$5,456,592
Nuclear Regulatory Commision	$270,000	$139,948	$139,948
Professional/Academic Assoc & Soc.	$517,040	$1,042,859	$1,042,859
Research Organization	$762,595	$350,768	$350,768
Social Security Administration	$2,620,421	$1,849,991	$1,849,991
State Non-VA	$184,253	$310,544	$310,544
State VA	$28,718,405	$24,143,272	$24,143,272
Default Sponsor Type		$53,745	$53,745
National Endowment for the Humanities		$34,317	$34,317
TOTAL	$255,461,169	$231,370,662	$231,370,662
Capital Construction/Renovation	$3,098,000		
Clinical Trial (Federal)	$6,806,123	$7,240,913	$7,240,913
Clinical Trial (Industry)	$13,101,800	$10,378,047	$10,378,047
Equipment	$997,268	$232,151	$232,151
Fellowship	$1,818,129	$1,255,068	$1,255,068
Intergovernmental Personnel Assignment	$241,291	$84,169	$84,169
Master Agreement	$20,616	$109,568	$109,568
Other	$64,139,665	$59,325,256	$59,325,256
Outreach	$24,500	$235,998	$235,998
Research	$129,909,233	$119,592,586	$119,592,586
Training	$35,304,544	$32,916,906	$32,916,906
TOTAL	$255,461,169	$231,370,662	$231,370,662

VIRGINIA COMMONWEALTH UNIVERSITY

Number of Proposals by Sponsor Type for FY2010

Starting Unit: Virginia Commonwealth University ; Reference Date: Entire Fiscal Year ; OSP Team: <all teams>

Sponsor Type	Quantity
College/University	209
Default Sponsor Type	1
Department of Defense	85
Department of Education	57
Department of Energy	11
Department of Health & Human Services	59
Department of Justice	2
Department of Labor	2
Department of State	3
Environmental Protection Agency	3
Federal	65
Federal Laboratory	1
Foreign Government	14
Foundation	138
Hospital	21
Industry	274
Local Non-VA	1
Local VA	26
National Aeronautics & Space Agency	7
National Endowment for the Humanities	1
National Institutes of Health	798
National Science Foundation	176
Non-Profit	208
Nuclear Regulatory Commision	5
Professional/Academic Assoc & Soc.	39
Research Organization	18
Social Security Administration	28
State Non-VA	3
State VA	206
Total:	**2461**

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 _____ **No Acronyms**

Phone # _____ E-mail: _____

Due Date: _____
Receipt Date ☐ Postmark ☐
E-Submission* ☐

Research ☐ **Clinical Trial** ☐ **Fellowship** ☐ _____ **Training** ☐ **Other** ☐ _____
(Name of Fellow)

-If research or clinical trial, indicate:
Basic ☐ Applied ☐ Developmental ☐

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 ☐ TFP ☐ FUP ☐

Budget Information

	Year One	Year Two	Year Three	Year Four	Year Five	Project Total
Direct						$0.00
Indirect						$0.00
Subtotal Sponsor	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Cost Share *						$0.00
Total	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00

*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.

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)

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 ☐ Other: _____

☐ Core: _____

*** Core facility listing can be found at 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	
☐								Signed ☐	Sal Esc ☐
☐								Signed ☐	Sal Esc ☐
☐								Signed ☐	Sal Esc ☐
☐								Signed ☐	Sal Esc ☐
☐								Signed ☐	Sal Esc ☐

*Please use the Continuation Page for additional Co PI listings (click here to link to the Continuation Page)

COMPLIANCE DATA

The proposal enclosed involves the following:

Yes	No	Don't Know		Yes	No	Don't Know		Yes	No	Don't Know	
☐	☐	☐	Human Subjects Research[1] (If yes, complete table below)	☐	☐	☐	Radioactive Materials[4,5]	☐	☐	☐	Clinical Trial
☐	☐	☐	Animal Use[2] (If yes, complete table below)	☐	☐	☐	Recombinant DNA, Select Agents or other biohazards[4,5]	☐	☐	☐	Research is subject to export controls
☐	☐	☐	Foreign Nationals	☐	☐	☐	Company Confidential Information will be provided	☐	☐	☐	Sponsor is foreign-owned company or foreign government
☐	☐	☐	Restrictions on Publication or Intellectual Property Rights	☐	☐	☐	International Program	☐	☐	☐	Program Income
☐	☐	☐	Retired faculty participation	☐	☐	☐	Subcontracts or subrecipients[6] (external)	☐	☐	☐	Wet lab space
☐	☐	☐	Rented off campus facility	☐	☐	☐	Subaccounts (internal)[6]	☐	☐	☐	Additional/New space
☐	☐	☐	Delivery of anything more than technical report	☐	☐	☐	NSF Funds- RCR Training Required	☐	☐	☐	NIH Funds- RCR Training Required
☐	☐	☐	HIPAA Covered Data[3]								

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	
☐	☐	All applicable items contained in the **Compliance Data** 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.).
☐	☐	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.
☐	☐	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.
☐	☐	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.
☐	☐	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.).
☐	☐	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.

Principal Investigator/Date	☐ A copy of this proposal has been delivered to my Department Chair for review. (Check Box)	Dean/Date
Co-Investigator/Date	☐ A copy of this proposal has been delivered to my Department Chair for review. (Check Box)	Dean/Date
Co-Investigator/Date	☐ A copy of this proposal has been delivered to my Department Chair for review. (Check Box)	Dean/Date
Services Investigator/Date	**Appropriate approvals obtained (see above). Approved on behalf of the University:**	Dean/Date
Clinical Trials Office/Date* (*Only if Clinical Trial)	University Official/Date	

The National Science Foundation conducts an annual survey entitled "Higher Education Research and Development Survey" to collect data on research and development activities at higher education institutions. National rankings and a variety of other reports are generated from the data collected. In prior years, all data was reported from existing data in University-wide systems. We have been notified that several new survey questions will be included in this year's survey, and we will be required to collect some information on existing awards to be able to properly complete it.

The survey now asks us to provide R&D expenditures broken down into the following categories:

Basic research – Research undertaken primarily to acquire new knowledge without any particular application or use in mind
Applied research – Research conducted to gain the knowledge or understanding to meet a specific, recognized need
Development – The systematic use of the knowledge or understanding gained from research direct toward the production of useful materials, devices, systems, or methods, including the design and development of prototypes and processes.

Examples		
Basic research	Applied research	Development
A researcher is studying the properties of human blood to determine what affects coagulation	A researcher is conducting research on how a new chicken pox vaccine affects blood coagulation	A researcher is conducting clinical trials to test a newly developed chicken pox vaccine for young children
A researcher is studying the properties of molecules under various heat and cold conditions	A researcher is investigating the properties of particular substances under various heat and cold conditions with the objective of finding longer lasting components for highway pavement.	A researcher is working with state transportation officials to conduct tests of a newly developed highway pavement under various types of heat and cold conditions.
A researcher is studying the heart chambers of various fish species.	A researcher is examining various levels of a toxic substance to determine the maximum safe level for fish in a stream.	A researcher has a contract with the U.S. government to design a new stream monitoring system that will incorporate the latest research findings on toxicity levels for fish.

In a few weeks, we will be sending investigators who had active research or clinical trial awards in FY10, a survey for each award asking that it be designated as basic research, applied research, or development. We will also begin collecting this information on each new proposal submitted (via our internal approval form) to eliminate the need for this type of survey in the future.

NCURA/EARMA Exchange

Erica M Lawler

Post Award Manager

Trip Basics

- When? 14th August – 27th August
- Where? Karolinska Institutet Stockholm, Sweden
- Why? US-EU Research Administrator Information Exchange

Karolinska, by the Numbers

- Founded in December 1810 by royal decree
- Student Population: 6,000 combined undergrad and Master's students, 2,000 doctoral candidates
- 2 Campuses: Solna & Huddinge + Karolinska University Hospital
- 5 Nobel Prizes in Physiology or Medicine awarded to KI researchers

Karolinska by Discipline

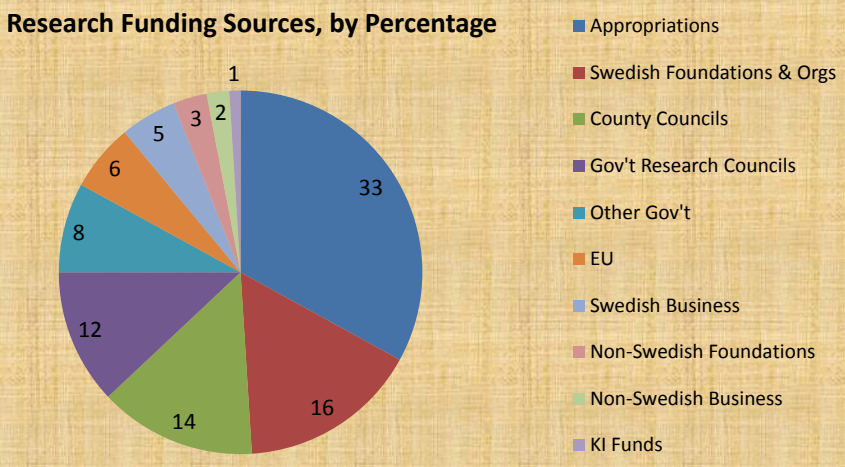
- 100% Medical University
- 22 Departments, **22 F&A Rates**
- Many Academic Departments have a matching clinical side in the hospital
- Met with Staff & Researchers from both Academic & Clinical Neuroscience as well as the Dean of Psychiatry

KI Research Funding

- 2009 Research budget, KI Solna Campus: 1.094 Billion SEK ($152,755,000 USD)
- 2009 Research budget, KI Huddinge Campus: 773 Million SEK ($107,943,000 USD)
- 2009 Research budget, Karolinska U Hospital: 1.049 Billion SEK ($146,472,000 USD)
  - Grand Total: 2.916 Billion SEK, $407,190,000 USD

KI Research Funding

- 83% of KI Income is from Research



KI Research Support

- Grants Office: 6 Combined Pre and Post Award Support plus 2 Career Services staff
- Legal Office: 4 Lawyers providing legal counsel on foreign agreements (Ex. Subcontracts to KI and EU multi-party contracts)
- Internal Audit: 2 auditors acting as compliance consultants
- Departmental Research Administrators

KI/VCU Comparison

KI Research Office

- Majority of staff hold PhDs and moved to central after being researchers
- Broad-Spectrum Pre-award support, EU & some NIH Post Award Support
- No centrally-administered grants database
- Swedish law prohibits IRB or IACUC

VCU Office of Research

- Majority administrative staff, few researchers
- Life-cycle centralized support from application to close out
- We all know and love VCUeRA
- IRB and IACUC panels accredited and allowable

European Union Framework Program 7 (2007 – 2013)

Funding Sources: Payments from 27 member states + 10 Affiliated countries
~ Sweden gets back more than it pays into EU

• 15% mandated to go to Small and Medium Enterprises (Employees <250)

Cooperation: 10 fields, Ex: Health, Food, Nanotechnology, Social Sciences, Environment, etc.
People: Training, Mobility, Development
Ideas: Investigator-driven research
Capacities: Call-specific application and objectives

Cooperation	**People**
Multi-partner involvement, 32.413bn€	Marie Curie Actions 4.7bn€
Ideas	**Capacities**
EU Research Council 7.5bn€	Catch-all Category 4.097bn€

EURATOM 2.751bn€

Joint Research Center 1.751bn€

http://cordis.europa.eu/fp7/home_en.html

So, what does it mean for VCU?

Marie Curie Actions

- International Incoming Fellowships: Any Nationality, 12- 24 mos at EU host institution
- International Outgoing Fellowships: VCU can host EU researcher for 12- 24 mos

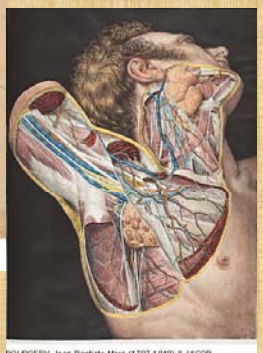
European Research Council Grants

- Starting Grants: 2-7 yrs after PhD= Starter, 7-12 yrs= Consolidator
  - Establishment of excellence
  - **1.5 M€ + .5M€ moving funds for 5 years**
- Advanced Grants: Any nationality, age, or field.
  - 10 yr research track record
  - Pursuit of high risk/high gain research
  - **2.5 M€ + 1 M € moving & equipment funds for 5 years**

VCU is eligible for EU Funding under FP7!!!

Waldemarsudde Medical Illustrations

- Significant portion of exhibition from KI's Medical Library



BOURGERY, Jean-Baptiste Marc (1797-1849) & JACOB, Nicolas Henri (1781-1871), Illustrator Traité complet de l'Anatomie de l'Homme, comprenant l'Anatomie chirurgicale et la Médecine opératoire. Foto: Hagströmerbiblioteket, Karolinska Institutet

Trivia About KI

- Tuition was instituted for the first time ever this year, but only for non-EU students
- Since 1895, the Nobel Assembly at KI has awarded the Nobel Prize for Physiology or Medicine
- Karolinska Development, the Tech Transfer offshoot from KI, publicly trades its start up businesses on the Swedish Stock Market

VCU
Office of Sponsored Programs
Office of Research

Committee on the Administration of Research's
Research Administration and Compliance Meeting
OSP Updates:
VCUeRA Workflow
September 15, 2010

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VCUeRA Workflow Updates

Presentation Topics:

- VCUeRA Workflow Diagrams:
  - Phase One – Proposal Process (implemented August 2009)
  - Phase Two – Pre Award Process (implemented January 2010)
  - Phase Three – Award Process (implemented May 13, 2010)
  - Phase Four –Post Award Process (Fall 2010 implementation)
- Just-in-Time Submissions
- Sponsored Projects Administration Certification Program

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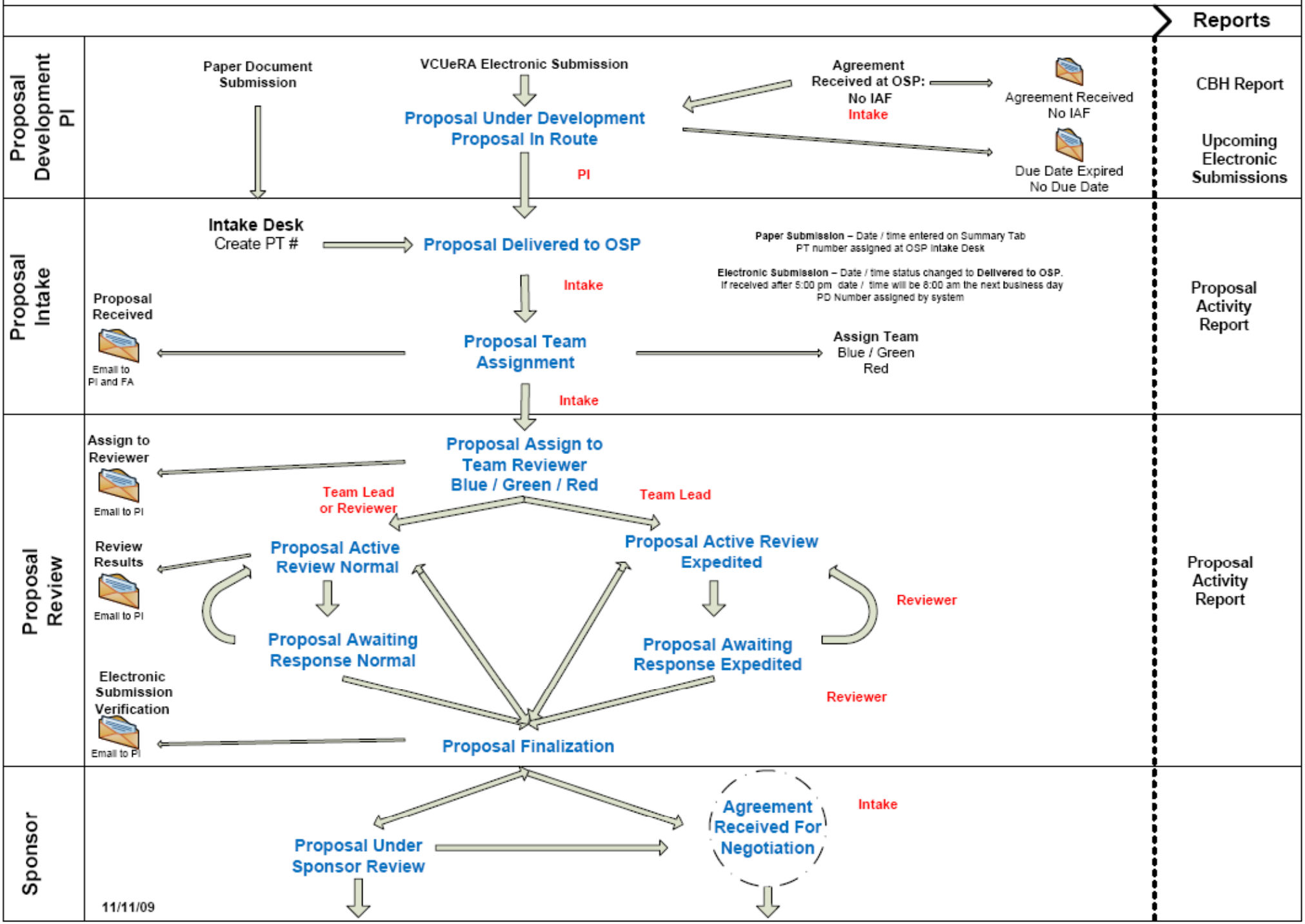
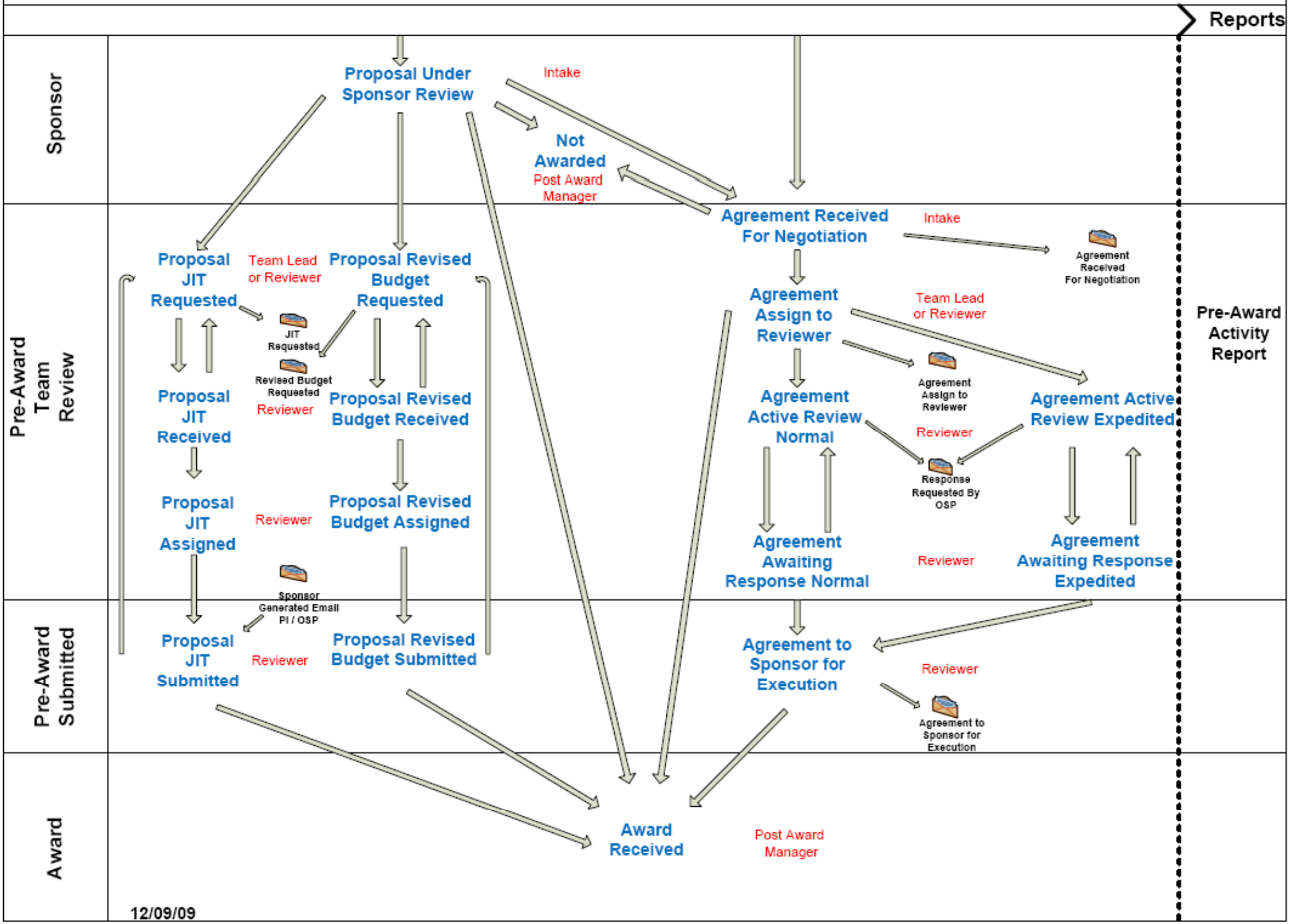
Office of Sponsored Programs Proposal Process

Implemented August 2009

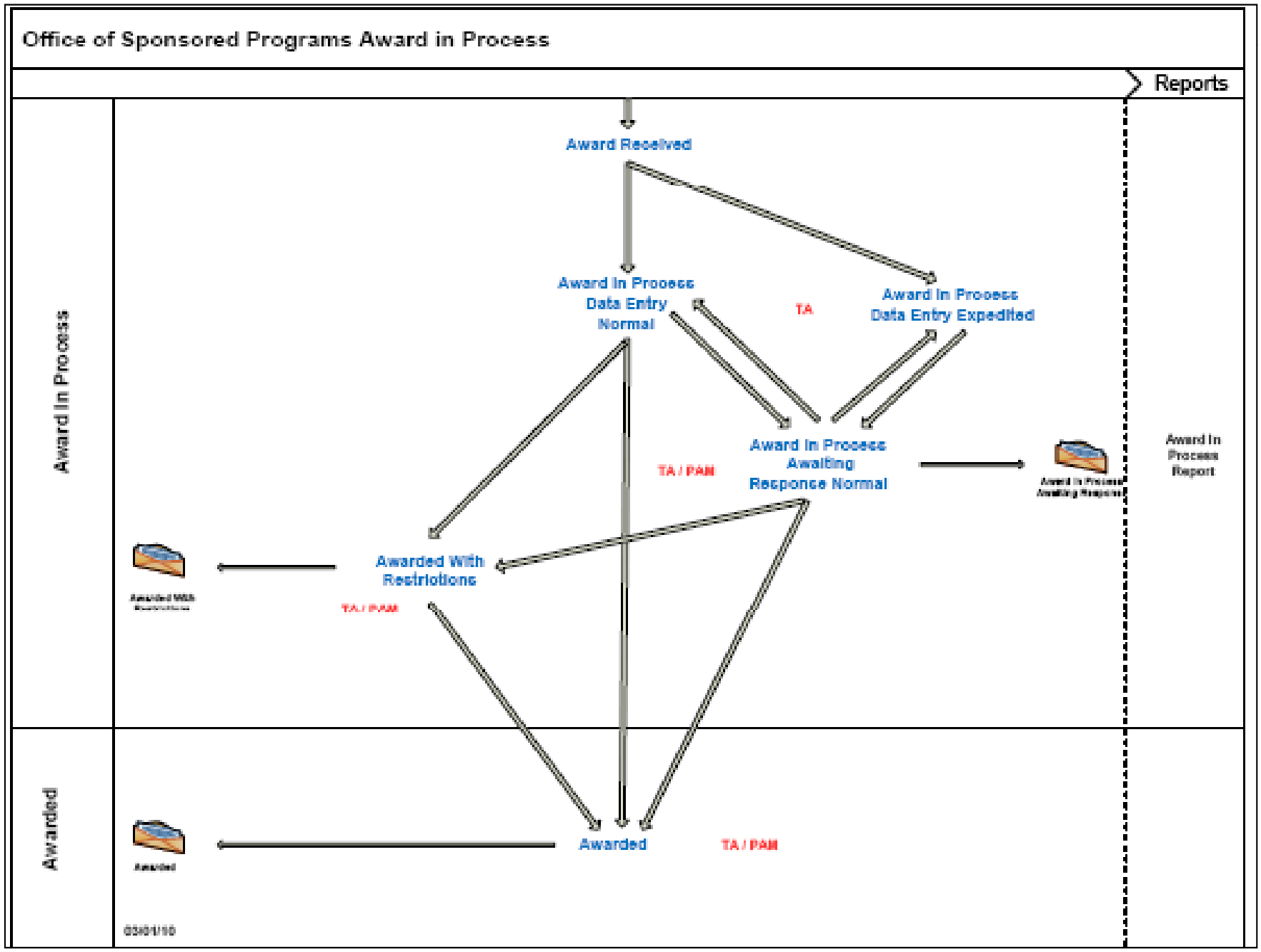


Office of Sponsored Programs Pre-Award Process

Implemented January 2010



Implemented May 13, 2010



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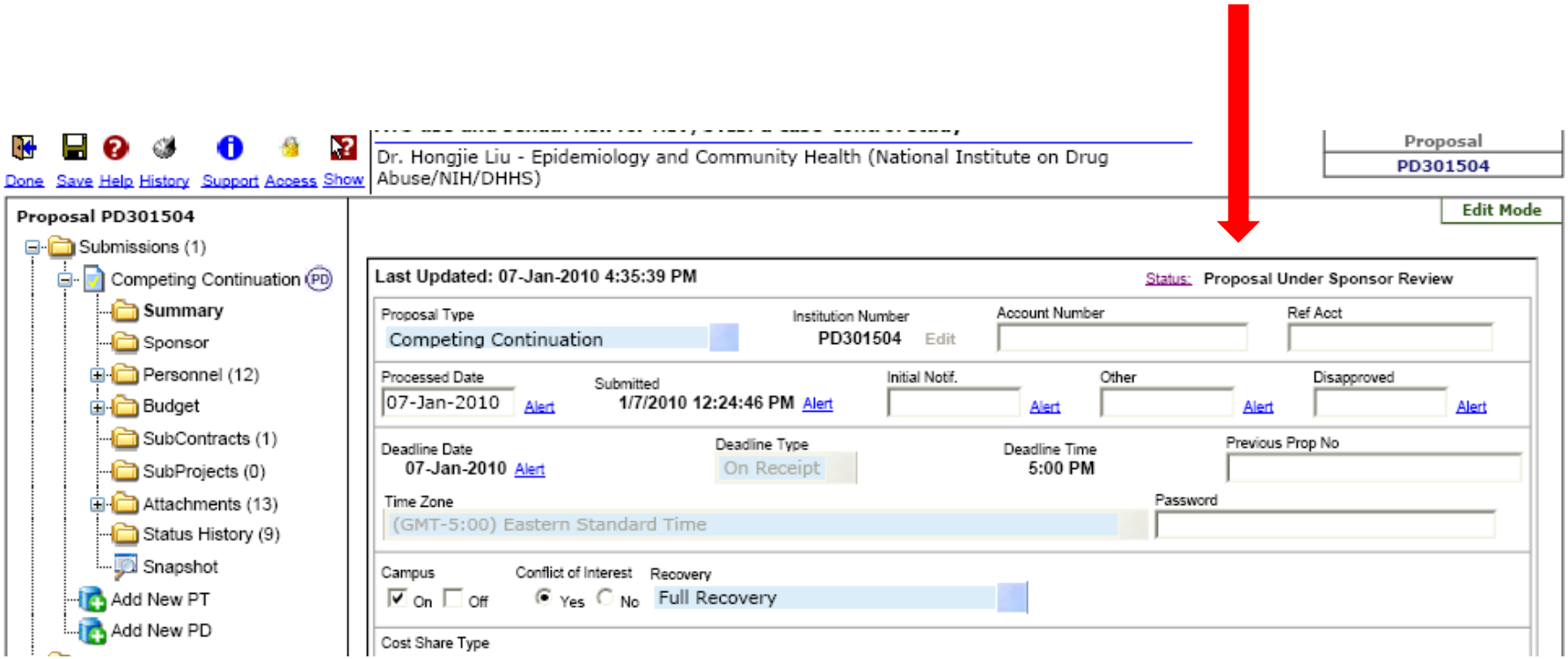
Status Inquiries:
First Check VCUeRA PT/PD record



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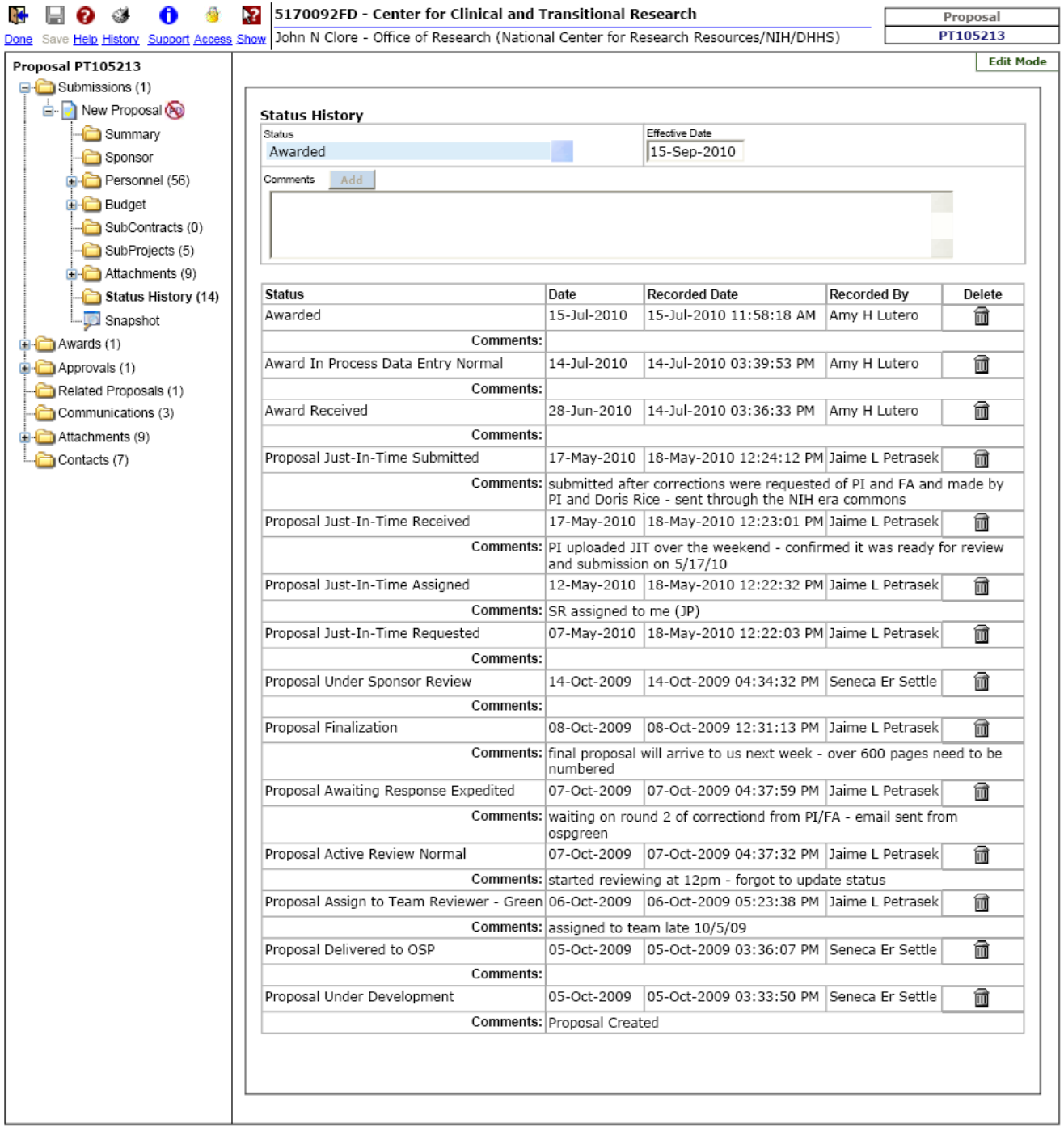
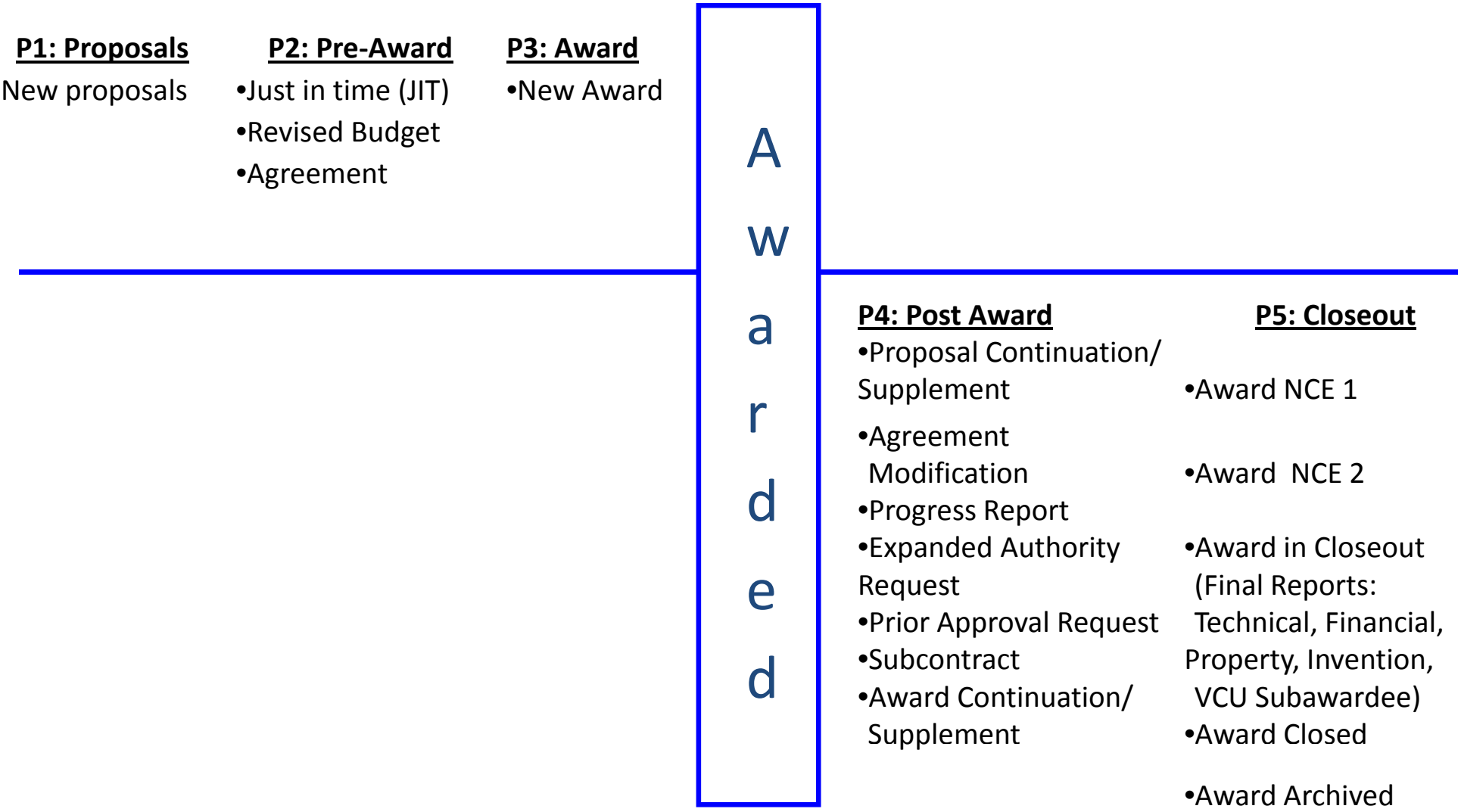
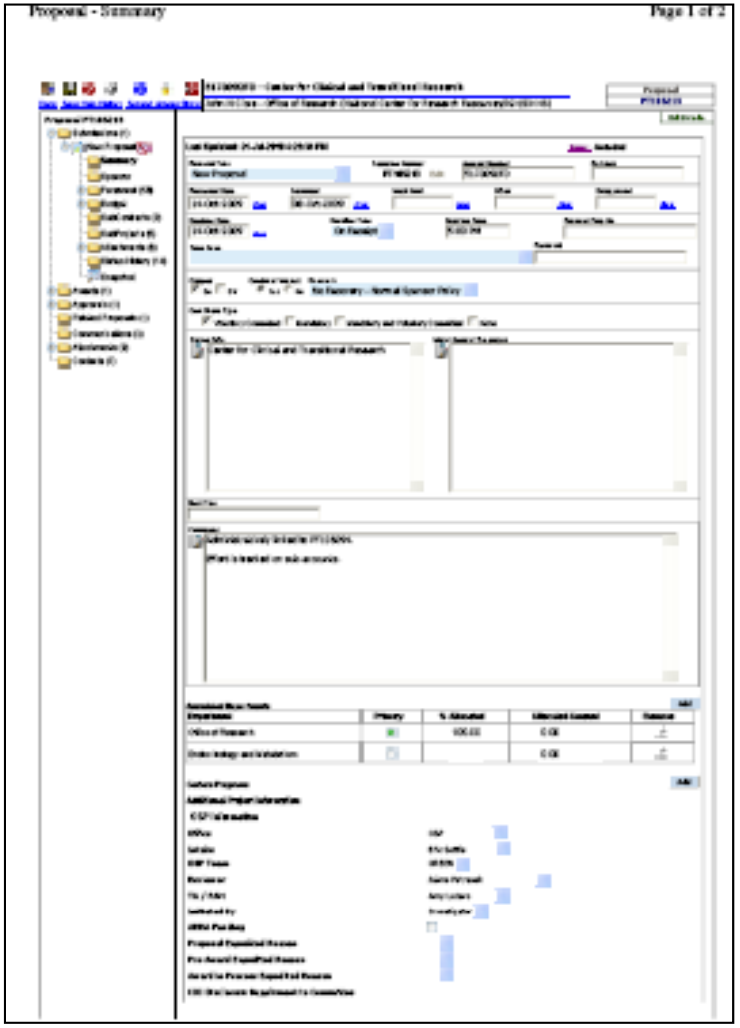
Status History:

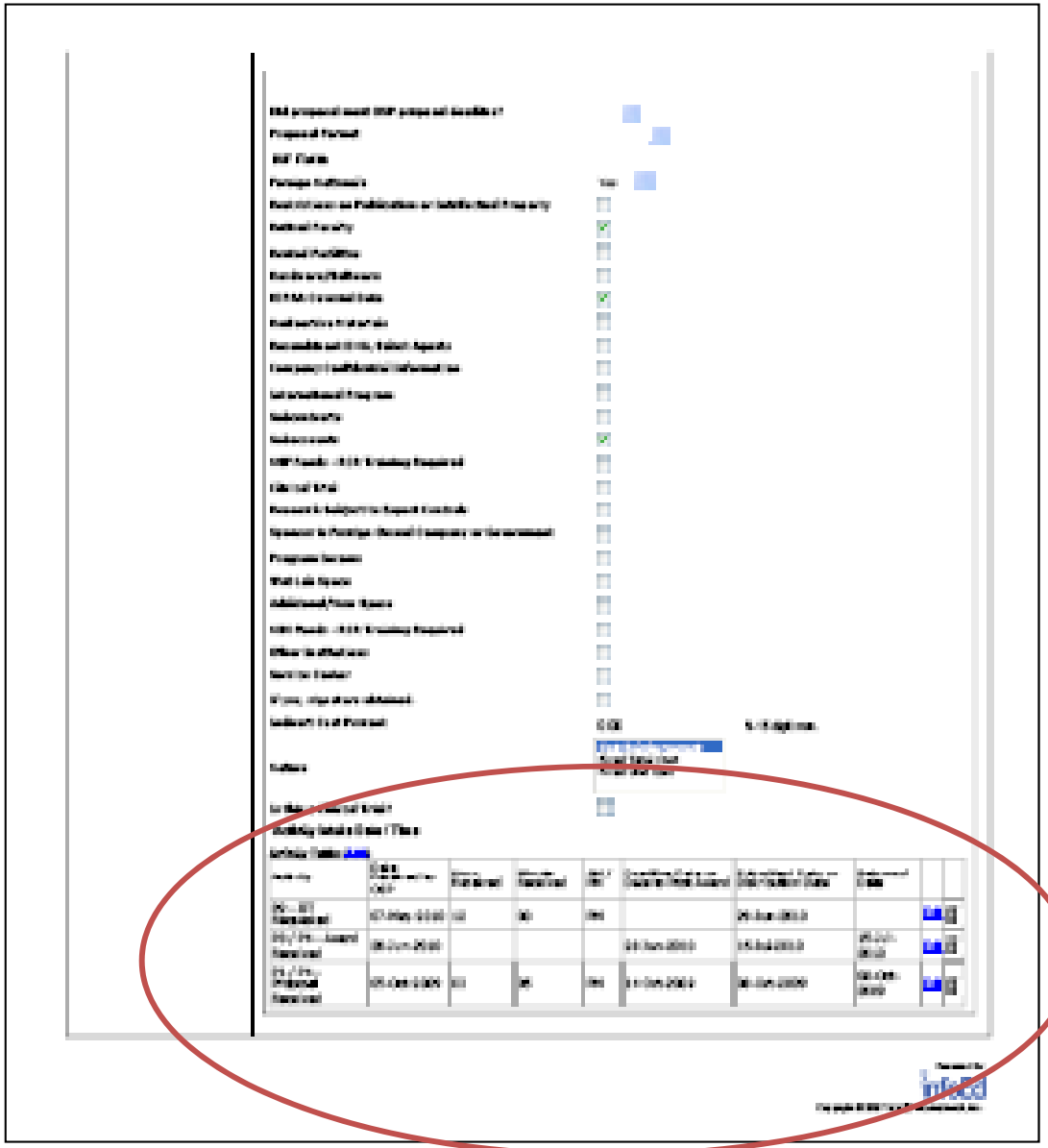


VCU OSP Sponsored Project Workflow Phases



VCUeRA Summary Screen





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OSP ACTIVITY TABLE GUIDE: Post Award Transactions (abbreviated for RACM)

Activity (who is responsible for checklist &/or review)	Date Received to OSP (P1-P3) or Awarded New Action Received (P4) (Hour/Minute AM/PM)	Deadline Date or Date to Post Award (P3)	Descriptor (P4)	Awarded New Action Review (P4)	Awarded New Action Awaiting Response (P4)	Submitted Date (P1) or Date Processed (P2) or Date Distributed (P3) or Awarded New Action Completed (P4)	Status
P4 Proposal Continuation/ Supplement (Intake>Teams)	Date IAF package arrives to OSP ready for review (Intake enters date)	Sponsor published due date, if applicable	Descriptor, i.e. minority supplement, additional year funding, etc.	Date OSP reviewer commences review	Date OSP reviewer is awaiting response from PI, FA, etc.	Date proposal signed by VCU AOR (Intake enters date at finalization)	Awarded
P4 –Agreement Modification/ Supplement (Teams)	Date agreement mod arrives to OSP ready for review (Reviewer enters date)	Sponsor published due date, if applicable	Descriptor, i.e. increase in funds, decrease in funds	Date OSP reviewer commences review	Date OSP reviewer is awaiting response from PI, FA, etc.	Date fully executed mod is received back from sponsor (Post Award enters date)	Awarded
P4 –Expanded Authority Request (Teams or Post Award)	Date transaction arrives to OSP ready for review (Reviewer enters date)	n/a	Descriptor, i.e. NCE request	Date OSP reviewer commences review	Date OSP reviewer is awaiting response from PI, FA, etc.	Date action processed with sponsor (Post Award enters date)	Awarded
P4 –Prior Approval Request (Teams or Post Award)	Date transaction arrives to OSP ready for review (Reviewer enters date)	n/a	Descriptor, i.e. Change of PI, Carryforward request, etc.	Date OSP reviewer commences review	Date OSP reviewer forwards request to sponsor	Date sponsor accepts or rejects request (Post Award enters date)	Awarded
P4– Progress Report (Teams)	Date transaction arrives to OSP ready for review (Reviewer enters date)	Sponsor published due date, if applicable	Descriptor, i.e. Y2 progress report	Date OSP reviewer commences review	Date OSP reviewer is awaiting response from PI, FA, etc.	Date progress report is submitted to sponsor by OSP (Team enters date)	Awarded
P4 –Subaward (Post Award)	Date transaction arrives to OSP ready for review (Post Award enters date)	n/a	Descriptor, i.e. University of Vermont (name of our sub)- repeat if multiple subs	Date OSP Post Award commences drafting subaward	Date Post Award forwards agreement to subawardee for signature	Date of encumbrance and distribution of Direct Pay Form (Post Award enters date)	Awarded
P4 –Award Continuation/ Modification/ Supplement (Post Award)	Date fully executed award arrives to OSP ready to process in VCUeRA (Post Award enters date)	n/a	Descriptor, i.e. Y2 continuation	Date OSP Post Award processes authorized award in VCUeRA	Date OSP Post Award is awaiting response from PI, FA or sponsor	Date Post Award distributes award to PI/FA (Post Award enters date)	Awarded

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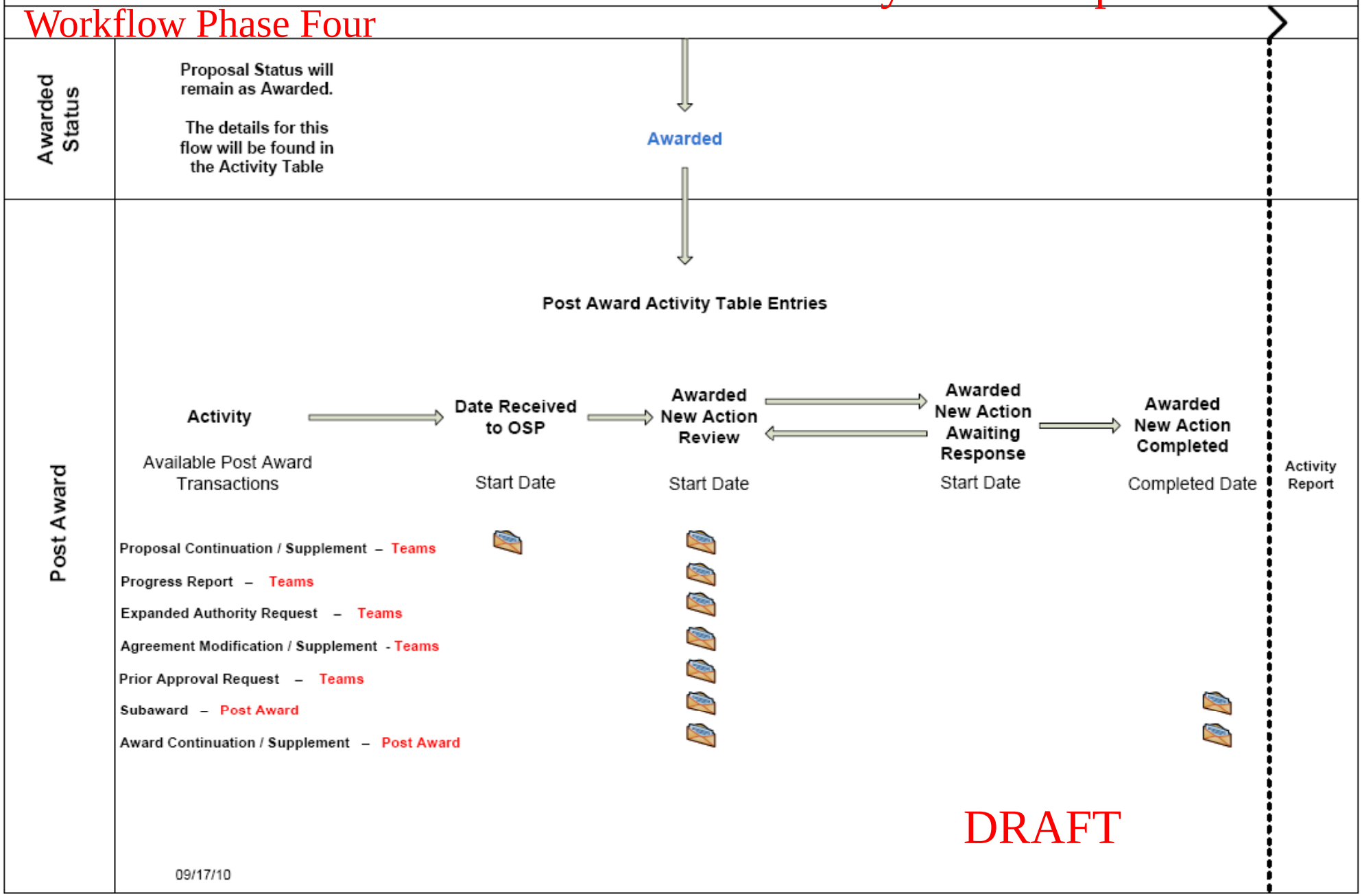
Office of Sponsored Programs Post Award

Currently in development

Workflow Phase Four



DRAFT

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Office of Sponsored Programs
Office of Research

Review of
NIH's Just-in-Time Submissions

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Just-in-Time (JIT)

- **"JIT"** is an acronym for **Just-In-Time** and refers to the application timeframe requiring applicants to send additional information to the NIH only if an award is likely.
- This process decreases the administrative burden for the 75%-80% of the applications that will not receive funding and provides NIH with the most current information "just-in-time" for award.
- NIH uses the **JIT** procedures for certain programs and award mechanisms; not all submitted applications will be subject to a **JIT**.
- A **JIT** generally calls for a limited amount of information to be submitted when an application is under consideration for funding, generally following peer review. Please note that a **JIT** is not the same as a call to submit supplemental materials.
- Remember – a request to submit JIT information is NOT a guarantee of an award.

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Who Should Submit a JIT?

When **"JIT"** is posted in the "Action" column of a PI's NIH eRA Commons account, it signifies that the application has completed the peer review process and has received a rank for which funding **MAY** be possible; HOWEVER:

- All PIs must wait to receive an official notice from NIH requesting JIT documentation.
- The JIT request from NIH may be received via fax, mail or email; if it is received by OSP, we will forward to the appropriate PI and FA on record and we will update the WorkFlow status on VCU ERA.
- JIT requires a Signing Official (SO) at your Institution to send the request to the NIH, be it through the NIH eRA Commons or OSP Team email. The JIT response should be prepared and submitted to OSP a **minimum of five full business days** prior to the NIH JIT due date. Please allow OSP additional time for review if the response due date falls on a major NIH deadline.

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What Information Will I Need to Submit to OSP for a JIT?

- A **JIT** report typically Includes:

  -Congruent Human subjects approvals (IRB)

  -Animal subjects approvals (IACUC)

  -Human subjects education certification

  -**ALL** Other Support for **ALL** Key Personnel

  -Other items as requested by sponsor

  (revised budget, revised Scope of Work, etc.)

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Just-in-Time (JIT): Other Support

KEY PERSONNEL – OTHER SUPPORT

A list of the most current ACTIVE and PENDING Other Support will be requested for all Key Personnel.

- Institute/Center (IC) scientific program and grants management staff will review this information before award to ensure the following
  1. Sufficient levels of effort are committed to the project.
  2. There is no scientific, budgetary, or commitment overlap.
- Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent/12 CAL MONTHS, **is not permitted**. Any potential overlap should be indicated in the JIT with a statement included as to how the affected Investigator plans to resolve the Overlap.

Note: **Each VCU Investigator is responsible for maintaining a current record of ALL Active and Pending Support**.

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Types of Overlap

- **Scientific overlap** occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.

- **Budgetary overlap** occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.

- **Commitment overlap** occurs when an individual's time commitment exceeds 100 percent/12 CAL MONTHS, whether or not salary support is requested in the application.

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What Types of Other Support Should I Include?

Other Support includes ALL CURRENTLY ACTIVE AND PENDING financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

- An Active Research Project is an awarded project that is not expired at the time of the JIT submission (this includes a project that is in a NO COST EXTENSION phase)
- A Pending Research Project is a submitted project that has not been awarded or rejected at the time of the JIT submission
- If support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.

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Which Investigators Should Submit Other Support Information?

- **Complete Other Support MUST be included for ALL Senior/Key Personnel.**
- Unless specifically requested, do not include Other Support for individuals listed as "Other Significant Contributors" unless their involvement has changed so that they now meet the definition of "Senior/Key Personnel.“
- Unless specifically requested, do not include Other Support for individuals listed as “Consultants” or “NON-KEY Personnel.”
- If an individual has no active or pending support, simply list their name and indicate “None.”

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What Should be Included on the Other Support Page?

Other Support: Instructions for Selected Items

- **Sponsor Project Number**: If applicable, include a code or identifier for the project.
- **Source**: Identify the agency, institute, foundation, or other organization that is providing the support.
- **Title**: Provide the Sponsor Approved Title of the Project.
- Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.
- **Dates of Entire Approved/Proposed Project**: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

While it is the PI's responsibility to maintain a current record of ALL Active and Pending Support, VCU OSP reviews what is submitted by the PI against what is listed in VCUeRA; a VCU Internal Project Number (PT or PD#) is helpful and may be requested.

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Other Support: Instructions for Selected Items

- **Annual Direct Costs**: In the case of an active multi-year project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.
- **Percent Effort/Person Months**: For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Person months should be classified as academic, calendar and/or summer. For a pending project, indicate the level of effort in person months as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.
- **Overlap**: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort.

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Sample "Other Support"

Program Director/Principal Investigator:
(Last, first, middle)

For New and Renewal Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. ***Include the principal investigator's name at the top and number consecutively with the rest of the application.*** The sample below is intended to provide guidance regarding the type and extent of information requested.
For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.
Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

Format

NAME OF INDIVIDUAL
ACTIVE/PENDING

Project Number (Principal Investigator) Source Title of Project *(or Subproject)* The major goals of this project are…	Dates of Approved/Proposed Project Annual Direct Costs	Person Months (Cal/Academic/ Summer)

OVERLAP *(summarized for each individual)*

Samples

ANDERSON, R.R.
ACTIVE

2 R01 HL 00000-13 (Anderson) — 3/1/1997 – 2/28/2002 — 3.60 calendar
NIH/NHLBI — $186,529
Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) — 4/1/1994 – 3/31/2002 — 1.20 calendar
NIH/NHLBI — $122,717
Ion Transport in Lungs

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) — 9/1/1996 – 8/31/2002 — 1.20 calendar
Cystic Fibrosis Foundation — $43,123
Gene Transfer of CFTR to the Airway Epithelium

The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) — 12/01/2002 – 11/30/2004 — 2.40 calendar
National Science Foundation — $82,163
Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

PHS 398/2590 (Rev. 06/09) Page _____ **Other Support Format Page**

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Sponsored Projects Administration Certification Program

©VCU 2010-2011 Office of Research/Office of Sponsored Programs

2010-2011 Program Summary

No. of students enrolled:	37
VCU Departments Represented	> 23
Number of Modules	5

Module Topics:
Module 1 - Pre Award
Module 2 - Compliance
Module 3 - Clinical Trials
Module 4 - Post Award Basics
Module 5 - Project Management

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2010-2011 Program Dates

On-line Content Open	August 2010
Module 1 Live Session	September 8, 2010
Module 2 Live Session	September 29, 2010
Module 3 Live Session	October 20, 2010
Module 4 Live Session	November 17, 2010
Module 5 Live Session	December 15, 2010
End/Certificate Presentation	January 2011

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September 15, 2010

Federal Updates

NIH eSNAP Changes

- Effective August 1, 2010
  - All eligible grants MUST submit electronically through the NIH Commons
  - Progress Reports are due 45 days prior to next budget start date
  - IRB and IACUC approval dates no longer required
  - Check Section II Terms and Conditions of NOA to determine whether SNAP provisions apply

xTRAIN

- Effective January 1, 2011
  - All appointment forms (PHS 2271) and termination notices (PHS 416-7) must be submitted via xTRAIN
  - Two training sessions have already been held
  - If interested in a training session, please contact Jose Alcaine at jgalcaine@vcu.edu

NIH Post-Submission Application Materials Policy

- Effective for applications submitted on or after September 25, 2010
  - Only for unforseen administrative issues
  - Revised budget page(s) (change in budget request due to new funding or institution acquisition)
  - Biographical sketches (change in senior/key personnel due to the loss of an investigator)
  - Letters of support or collaboration resulting from a change in senior/key personnel due to the loss of an investigator

Acceptable Post-Submission Materials

- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (PI moved to another university)
- New of an article accepted for publication

Unacceptable Post-Submission Materials

- Updated Specific Aims or Research Strategy
- Late-breaking research findings
- Supplement pages – information not contained in the existing application
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the loss of an investigator

Exceptions

- Applications in response to RFAs with only one due date – follow former policy
- Applications for training grants – new guidance to be issued
- Certain FOAs may allow certain other types of materials to facilitate the goals of the program. Guidance must be included in the FOA.

Format and AOR Concurrence

- Font size, margins, form pages all apply.
- If not on a form page, limited to one page.
- If subprojects or cores, each is allowed explanations or letters but each limited to one page.
- AOR must send materials directly to the SRO. An e-mail from the PD/PI with a "cc" to the AOR will no longer be accepted.

Error Correction Window Eliminated

- Applies to all NIH, AHRQ and NIOSH applications
- Effective for applications submitted on or after January 25, 2011
- All Errors and Warnings must be addressed prior to 5 p.m. on the deadline date
- Two-day application viewing window unaffected
- Accommodations for Federal system issues will be made, if documented and verified