



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

School of Medicine

Research Administration

Quarterly Meeting

December 2014

Today's Topics

1. Notifications – Important Changes
2. Post – Award Topics
3. Pre-Award Topics
4. Questions??

Notifications

NIH & AHRQ require use of a new biosketch format

NOT-OD-15-032

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html>

- Require use of the new format for applications submitted for due dates on or after May 25, 2015.
- Applicants are encouraged to submit using the new biosketch format for due dates on or after January 25, 2015, if they wish.
- New format extends the page limit for the biosketch from four to five pages.
- Allows researchers to describe up to five of their most significant contributions to science, along with the historical background that framed their research.
- Researchers will be allowed to include a link to a full list of their published work as found in a publicly available digital database such as MyBibliography or SciENcv.

Notifications

NIH Modification to Guidance on Marking Changes in Resubmission Applications

NOT-OD-15-030 (Release 12/4/14)

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-030.html>

NIH removed the requirement to identify 'substantial scientific changes' in the text of a Resubmission application by 'bracketing, indenting, or change of topography'

Effective immediately, it is sufficient to outline changes to the Resubmission application in the Introduction attachment.

Notifications

Reminder related to updated NIH Resubmission policy

NOT-OD-14-082

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-082.html>

Updated policy allowed an applicant to submit the same idea under a new application (A0) following an unsuccessful resubmission application (A1).

When Investigators choose to do this please remember:

- You cannot reference any previous application in **any part** of the new application. (Not in specific aims, not in cover letter, not anywhere!)
- Use reviewer feedback to improve the application, just DO NOT reference a prior submission anywhere in the NEW application.

Notifications

NIH Clinical Trial Definition Change

NOT-OD-15-015

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>

“A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”

- Revisions is designed to make distinction between clinical trials and clinical research clearer.
- VCU is adopting this definition of a clinical trial.
- Note what previously termed observational CT is now clinical research.

Notifications

VCU New Mandatory Training Requirement

Applies to: Study personnel on clinical trial protocols.

Effective: February 1, 2015

Requirement: All study personnel* listed on a new or continuing review IRB protocol involved in executing a drug, device, biologic and/or behavioral intervention that meets the NIH definition of clinical trial are required to complete the Good Clinical Practice (GCP) module through the Collaborative Institute Training Initiative (CITI) course. Currently this training will be required every 3 years.

*Study Personnel: Individuals listed on the IRB protocol. This includes all VCU and VCUHS employees, all VCU students and Community Research Partners that are involved with clinical interventions.

Go to www.citiprogram.org and create your account or log in.

Please use your VCUeID and vcu e-mail address during the registration process.

Notifications

SOM Pool Account Policy Coming Soon

A policy has been developed and is in review by VPHS and VCU Finance and Administration to be incorporated as a local policy for SOM.

The university is expected to develop its own BOV approved policy in the near future.

The intent of the policy is to clearly state that pool account funds are to be used for research or research administration/support purposes.

Look for it coming soon .


Post- Award Updates

Dashboard Tip:

Need to create custom projections or budgeting for a PI?

Use “Total Cost Summary by Account Category” screen in the PI Dashboard to download current expense data to Excel and update projections as needed for a PI.

Other Operating Costs				
Services	30,807.00	7,500.00	0.00	23,307.00
Supplies	0.00	59,999.99	0.01	(60,000.00)
Travel and Education	7,000.00	1,548.70	0.00	5,451.30
Subtotal Other Operating Costs	37,807.00	69,048.69	0.01	(31,241.70)
TOTAL DIRECT EXPENSES	493,541.33	130,215.17	142,336.92	220,989.24
F&A				
Facilities and Administrative Costs	259,345.36	63,376.02	0.00	195,969.34
TOTAL DIRECT AND INDIRECT EXPENSES	752,886.69	193,591.19	142,336.92	416,958.58

 [Export to Excel](#)

Post-Award Updates

Dashboard Tip:

Need to create custom projections or budgeting for a PI?

TOTAL COST SUMMARY BY ACCOUNT CATEGORY					
INDEX=541706 : 1R01MH100549 01					
BUDGET PERIOD=09/01/2014-08/31/2015					
EXPENSE CATEGORY	TOTAL BUDGET	TOTAL EXPENSES TO DATE	TOTAL COMMITMENTS	AVAILABLE BALANCE	
Personnel Costs					
Labor	405,156.33	0	0		Current % effort
Aggen, Steven H.	0	325.09	7,612.52		12%
Bacanu, Silviu-Alin	0	1,221.87	28,612.35		25%
Kendler, Kenneth S.	0	1,135.53	26,563.63		15%
Mikell, Linda B.	0	153.17	3,586.73		5%
Neale, Michael C.	0	378.34	8,859.69		5%
Noble, Joey W.	0	228.81	5,357.73		10%
Reimers, Mark A.	0	875.25	20,495.20		20%
	0	301.29	7,054.97		5%
	0	820.46	19,212.44		25%
Fringe	50,578.00	1,865.86	43,683.09		
Subtotal Personnel Costs	455,734.33	7,305.67	171,038.35	277,390.31	
Other Operating Costs					
Services	30,807.00	5,000.00	0		
Supplies	0	0	60,000.00		
Subgrants	131,057.00	0	131,057		< Year 2 subaward to Oxford University
Travel and Education	7,000.00	0	0		
Subtotal Other Operating Costs	168,864.00	5,000.00	191,057.00	-27,193.00	
TOTAL DIRECT EXPENSES	624,598.33	12,305.67	362,095.35	250,197.31	< projected available balance as of 8/31/15

First, add in formulas to sum subtotals and total expenses

Post- Award Updates

Dashboard Tip:

Need to create custom projections or budgeting for a PI?

TOTAL COST SUMMARY BY ACCOUNT CATEGORY					
INDEX=541706 : 1R01MH100549 01					
BUDGET PERIOD=09/01/2014-08/31/2015					
EXPENSE CATEGORY	TOTAL BUDGET	TOTAL EXPENSES TO DATE	TOTAL COMMITMENTS	AVAILABLE BALANCE	
Personnel Costs					
Labor	405,156.33	0	0		Current % effort
Aggen, Steven H.	0	325.09	7,612.52		12%
Bacanu, Silviu-Alin	0	1,221.87	28,612.35		25%
Kendler, Kenneth S.	0	1,135.53	26,563.63		15%
Mikell, Linda B.	0	153.17	3,586.73		5%
Neale, Michael C.	0	378.34	8,859.69		5%
Noble, Joey W.	0	228.81	5,357.73		10%
Winters, Mark A.	0	875.25	20,495.20		20%
	0	301.29	7,054.97		5%
	0	820.46	19,212.44		25%
Fringe	50,578.00	1,865.86	43,683.09		
Subtotal Personnel Costs	455,734.33	7,305.67	171,038.35	277,390.31	
Other Operating Costs					
Services		5,000.00	0		
Supplies	0	0	60,000.00		
Subgrants	131,057.00	0	131,057		< Year 2 subaward to Oxford University
Travel and Education	7,000.00	0	0		
Subtotal Other Operating Costs	168,864.00	5,000.00	191,057.00	-27,193.00	
TOTAL DIRECT EXPENSES	624,598.33	12,305.67	362,095.35	250,197.31	< projected available balance as of 8/31/15

Then, manually add in other commitments and effort %s of personnel, if needed

Post- Award Updates

Dashboard Tip:

Need to create custom projections or budgeting for a PI?

1 As of 9/17/14		TOTAL COST SUMMARY BY ACCOUNT CATEGORY			
2 CONVERGE		INDEX=541706 : 1R01MH100549 01			
3		BUDGET PERIOD=09/01/2014-08/31/2015			
4					
5	EXPENSE	TOTAL	TOTAL	TOTAL	AVAILABLE
6	CATEGORY	BUDGET	EXPENSES	COMMITMENTS	BALANCE
7			TO DATE		
8	Personnel Costs				
9	Labor	405,156.33	0	0	Current % effort
10	Aggen, Steven H.	0	325.09	7,612.52	12%
11	Bacanu, Silviu-Alin	0	1,221.87	28,612.35	25%
12	Kendler, Kenneth S.	0	1,135.53	26,563.63	15%
13	Mikell, Linda B.	0	153.17	3,586.73	5%
14	Neale, Michael C.	0	378.34	8,859.69	5%
15	Noble, Joey W.	0	228.81	5,357.73	10%
16	Reimers, Mark A.	0	875.25	20,495.20	20%
17	Riley, Brien P.	0	301.29	7,054.97	5%
18	Webb, Bradley T.	0	820.46	19,212.44	25%
19	Fringe	50,578.00	1,865.86	43,683.09	
20	Subtotal Personnel Costs	455,734.33	7,305.67	171,038.35	277,390.31
21	Other Operating Costs				
22	Services	30,807.00	5,000.00	0	
23	Lab animal costs starting in February 2015			12000	
24	Supplies	0	0	60,000.00	
25	Subgrants	131,057.00	0	131057	< Year 2 subaward to Oxford University
26	Travel and Education	7,000.00	0	0	
27	Subtotal Other Operating Costs	168,864.00	5,000.00	203,057.00	-39,193.00
28					
29	TOTAL DIRECT EXPENSES	624,598.33	12,305.67	374,095.35	238,197.31 < projected available balance as of 8/31/15
34					

You can add in more detailed budget categories for future commitments

Post- Award Updates

When a PI is in a terminated status and still has outstanding monthly expense reports in the Dashboard:

The School of Medicine will contact the employee's department and ask that an approver sign-off on PDF copies of the uncertified monthly expense reports. Once SOM has a copy of the department-approved expense reports, the electronic copies of the reports will be removed from the Dashboard and will no longer appear as past due.

Please continue to close out or change PI on grant indexes as soon as possible after the original PI has left VCU!

SOMPROPOSALS – Stats

From July 1 – Dec 4, 2014

- **554** reviews occurred (research, clinical research and clinical trials) – **18% increase** over same period in 2013
- **280** of those were reviewed *after* 9/30/14 or **51%**
- **39%** of the total reviews were to NIH

SOMPROPOSALS – Reminders

- Preferred method of delivery for “Paper” submissions **To** and **From** SOMPROPOSALS:
 - Electronically to our group email - SOMPROPOSALS@vcu.edu
 - The signed IAF and any accompanying documents will be returned *electronically* to the department to be included with their final package to OSP.
 - Any hard copy drop-offs should *not include original documents, especially those that require an Authorized Official signature*.
 - We will dispose of any paper documents remaining in our office after the proposal have been approved and returned to the department.

****This process is subject to change pending RAMS-SPOT implementation**

SOMPROPOSALS – Reminders

Deadlines: Submit completed application packages for Dean’s office review a **minimum of 7 business days** in advance of the sponsor’s published deadline.

- This allows at least **2 business days** for Dean’s office review prior to OSP’s required deadline of **5 business days**.

What the Dean’s office is confirming by signing the IAF:

PI Eligibility

Space

SOM Human Resources

Budget

Cost Share

VAMC Joint Appt. MOU

Compliance Documentation Checklist (and all applicable components)

Internal Subaccounts

- SOM strongly encourages use of internal subaccounts whenever an award budget is to be managed by multiple departments and especially multiple schools.
- Departments can use their discretion in determining what value is added by establishing a subaccount for “inconsequential” dollars (i.e. only 1% effort of a Co-I) in their area.
- If a SOM department is cost sharing their faculty member then internal subaccounts are required to allow for recovery of FACR to help off-set cost share cost for the department funding the cost share index.

Cost Sharing – Who's Responsible?

- The department that will be responsible for funding and managing the cost share must sign the Cost Share Authorization form.
- This is typically the home department (primary appointment) of the faculty member being cost shared.
- It is best practice to have cost sharing indexes associated with a sponsored research index be managed in the same fiscally responsible department.

Cost Sharing – What’s Required by SOM?

SOM requires a completed and signed Cost Share Authorization form if.....

- The proposal is “paper” then it is *always required* for all cost shared personnel.
- The proposal is “electronic” (InfoEd) it’s required for all SOM faculty to be cost shared that are outside of the fiscally responsible department.

*****This process is subject to change pending RAMS-SPOT implementation***

Budgeting – Areas to Improve

Research Patient Care

Costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers participating in research programs are allowable on NIH awards.

NIH Grant Policy Statement, Chap 19 – Research Patient Care Costs

http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch19.htm

Research patient care costs are excluded from the F&A base when budgeting for federal programs; meaning we do not calculate F&A on direct patient care costs when budgeting for federal studies. (MTDC base – part of our DHHS rate agreement)

Patient care costs are not excluded from F&A when developing budgets for industry clinical trials. (TDC)

Budgeting – Areas to Improve

Research Patient Care

What is considered research patient care?

Routine Services – regular room services, minor medical and surgical supplies, use of equipment and facilities.

Ancillary Services – special services such as x-ray, operating room, laboratory, pharmacy, blood bank, pathology, etc.

DOES NOT include reimbursement or payment to patients/volunteers/subjects for items of personal expense, patient travel, consulting physician fees, or any other direct payments to individuals. (On NIH applications these expenses are budgeted as “Other Expenses”)

DOES NOT include care that would have been incurred even if the research study did not exist. The patient and/or third-party insurance generally will provide for reimbursement of charges for “usual patient care”. (These costs are not budgeted)

Budgeting – Areas to Improve

VCUHS Personnel

VCUHS personnel, regardless of whether they are hospital employees or MCVP employees **ARE NOT VCU employees.**

- SOM Research Administration cannot verify the salary of these individuals in roles such as: housestaff, nurse coordinator, study coordinator, administrator, lab managers that are not VCU employees.
- These individuals should not be budgeted in the personnel category of a proposal budget.
- These individuals should be budgeted as Other Costs – Contractual Services. Both salary and applicable fringe.
- Appropriate agreements and approvals must be in place to support budgeting of VCUHS personnel/resources into a proposal.

Faculty that hold VCU academic appointments can be verified and are verified. PI eligibility rules apply when trying to budget a faculty member who has less than a full-time VCU appointment.

Questions??

We are always looking for feedback. If there are topics you would like to see discussed or ways we can improve these and other meetings or trainings....please let us know!

Proposal Submissions: SOMPROPOSALS@vcu.edu

Post Award: SOMRESADMIN@vcu.edu

Clinical Research/Trials: SOMCT@vcu.edu