



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

School of Medicine

Research Administration

Quarterly Meeting

May 2014

Today's Topics

1. Research Administration Updates
2. SOM Dean's Office Proposal Review/Approval
3. Fixed Price Closeouts – updated guidance documents
4. Clinical Research/Trials Updates

Research Administration Updates

Quick Updates:

- **OSP Team Assignment Changes**

Government/Non-profit side of OSP conducted work load assessment and made some SOM department assignment changes

- **VA MOU Updates**

MOU's for faculty conducting sponsored research with joint VCU/VAMC appointments need to be updated for FY15.

- **Research Dashboard**

Feedback is always needed on how to improve the PI and RA Dashboard portlets and reports. Want to participate in SOM focus group? Contact: Candice Weber, cweber@vcu.edu

SOM Dean's Office Proposal Review

Effective June 1, 2014 SOM Research Administration will assume responsibility for reviewing and approving all sponsored program applications and proposals on behalf of the Dean.

- Dr. Ford will be with us for the month of June to ensure the transition is smooth.
- Proposal drop-off/pick-up location will remain the same.
- Emailed proposals should be routed to:
SOMPROPOSALS@vcu.edu
- VPR office is working to ensure proper access for SOM RA group to review/approve VCUeRA submissions.

SOM Dean's Office Proposal Review

A sense of volume for SOM Dean's Office reviews:

- SOM faculty are involved in 85 proposals a month on average that require Dean's Office review/approval.
- Peak submission months can go as high as 120 proposals.
- About 60% of the applications that come through are paper based IAFs (non-VCUeRA)

SOM Dean's Office Proposal Review

So what will change when SOM Research Administration assumes this responsibility?

- Short Answer: Not a lot from a perspective of what will be reviewed, turn around times, and procedures for departments
- But what will change....
 - More than one SOM Dean-level reviewer
 - Standardizing email communications back to departments/PIs
 - We may have more questions in the beginning, especially as it relates to department based nuances
 - Updated proposal submission content is planned on our website as we identify areas where questions or issues frequently arise.

SOM Dean's Office Proposal Review

School Level Review

- School-level review and approval will confirm resources are available to complete the work proposed.
- Review focused primarily on administrative and financial components:
 - PI eligibility
 - Human resource allocations
 - Budget, budget narrative, cost share
 - Internal package is complete/accurate, required elements present

See – [SOM Review of Sponsored Program Applications and Proposals](#) – for further detail

SOM Dean's Office Proposal Review

Department Review

- **Deadlines** – Submissions must be to the Dean's office a minimum of 7 business days in advance of published deadline.
- **Expectation at Department Level**
 - Basic scientific review of proposals has occurred.
 - Application is complete in technical content and adheres to norms of proper scholarship and responsible conduct of research.
 - Appropriate COI investigators are designated.
 - Costs budgeted are reasonable and necessary for work proposed.
 - Alert SOM prior to submission if current space/facilities assigned to the investigator will be insufficient for work proposed.

See - [SOM Department Submission Checklist](#) – for further detail

SOM Dean's Office Proposal Review

SOM Review Procedure

- Emails will be coming from SOMPROPOSALS@vcu.edu
- **Three Options**
 - Approved, no comments
 - Approved, with comments
 - Returned for Correction

We will continue to make minor changes as does Dr. Ford when it will be more efficient than sending a submission back to the department.

SOM Dean's Office Proposal Review

Dr. Ford's Top Four Reasons Proposals are Returned to Departments

1. Budget Errors / Inconsistencies
2. Budgeting of Grad Student and Post Doc Costs
3. PI Eligibility (and others named in submission)
4. Required Documents Missing (we need a scope of work/abstract/protocol synopsis)

SOM Dean's Office Proposal Review

SOMPROPOSALS@vcu.edu

Remember the new email address should be used for:

1. Submitting proposals to the Dean's office
2. Correspondence related to a submission in process
3. Questions related to an upcoming submission
4. Questions related to the proposal submission and review process as a whole.

Questions, suggestions, comments may also be addressed to:
Margaret Phillips, MBA, CRA, Senior Research Administrator
mhphillips@vcu.edu or 628-6285

SOM Review of Fixed Price Close-outs

Two documents have been updated:

1. [Department Guidance for Submitting Fixed Price Closeouts for SOM Review/Approval.](#)
 - Updated for clarity regarding when SOM and/or VPHS approval is required.
 - Updated to remove some of the previously required documentation.
 - Updated to add requirements or clarify requirements for documentation required.
2. [School of Medicine Evaluation of Fixed Price Closeout Requests](#)
 - Updated for clarity regarding SOM process for evaluating fixed price close-outs.
 - Updated to clarify department/PI must request an exception to pool a cash balance that exceeds 10% of the total direct budget.
 - Updated to add statement about Department management of pool accounts.

NOTE: Clear your web browser's history to ensure you see the most up to date content on SOM Research Administration's website!

Questions, suggestions, comments may be addressed to:
SOMRESADMIN@vcu.edu

Clinical Research/Trials Updates

Recent SOM request for active study information:

- Request sent on May 2nd with a due date for response of May 16th
- Lists sent to departments/divisions contained protocols already in OnCore[®]
- Departments were asked to update this list; update info as needed for existing studies and add studies that fit within criteria provided in the request

Why?

- SOM has over 180 protocol records in OnCore[®]. We need to estimate how many more studies we may need to add.
- Our goal – to work with VCU CCTR to re-invigorate the roll-out of the OnCore[®] subject management console to our study teams .
- In order to develop an effective and realistic implementation plan we must get as current an inventory as possible of studies that may need to be fully built out in OnCore[®] for subject management.

Clinical Research/Trials Updates

Preliminary Results of the Data Request

- There are 181 protocol records in OnCore®, **another 152** studies were identified that will need to be evaluated for OnCore®.
- Critical fields with data issues:
 - VCUHS Billing (55% blank),
 - Expected end date (33% of studies not already in OnCore® blank)
 - Study Status – some responses do not provide enough information

Department “Readiness” for OnCore®

- We also need to prioritize roll-out of the system.
- Departments/Divisions that are eager to obtain access to the system and its benefits and can assure needed department resources will be available (coordinator time, research administrator time).
- Contact SOMCT@vcu.edu to discuss your areas readiness in more detail.

Clinical Research/Trials Updates

Upcoming Billing Compliance Deadline

For full details see CCTR web site:

[VCU-VCUHS joint clinical research/trial institutional billing procedure](#)

Reminder – July 1, 2014 – Deadline to ensure VCUHS has received required billing compliance documentation to be able to comply with the NCT # billing requirement

Forms relevant to ensuring billing compliance objectives are met:

- Completed Cost Coverage Analysis and Billing Grid
- CR and CT Billing Setup form
- Enrollment logs – submit now for existing studies and required update upon enrolling each new participant
- IAF Supplement for Clinical Research and Clinical Trial Billing form – *new studies*
 - Link http://www.research.vcu.edu/forms/index.htm#osp_forms

Clinical Research/Trials Updates

For Existing Studies:

- If VCUHS does not have the required documentation the study team must complete and send it.
- Work with SOMCT to complete CCA/Billing Grids – studies must be received by no later than June 15th
- In addition to CCTR instructions please copy SOMCT@vcu.edu on your submission of billing information for existing studies.

Link to steps to follow on CCTR website:

[What are the steps for VCUHS billing for existing clinical research and clinical trials?](#)

Clinical Research/Trials Updates

New Studies Require SOM CT Pre-Study Process

http://www.medschool.vcu.edu/about/finance/researchadmin/docs/SOM_new_study_process.pdf

Regardless of whether the study is internally or externally funded SOMCT must review/approve:

- Internal Budget
- VCU Ancillary Service and CRS/CRSU Service Agreements
- VCU Cost Coverage Analysis and Billing Grid
- CR & CT Billing Set-up form for VCUHS

Externally funded studies additionally require SOMCT to be provided:

- External (sponsor) budget, approve budget prior to finalizing negotiation.
- Contract (as applicable) to ensure budget and contract terms are congruent.

Clinical Research/Trials Updates

How does the SOMCT process interact with SOM Research Administration reviewing all sponsored program applications moving forward?

- Prepare IAF and all required documents and drop-off for review (or email SOMPROPOSALS@vcu.edu)
- We will be verifying that SOMCT pre-submission process was followed.

Clinical Research/Trials Updates

SOMCT is responsible for:

- School-level review and signature on the Cost Coverage Analysis package
- Approving the study budget prior to finalization with a sponsor
- Ensuring internal budget is adequate
- Reviewing all ancillary and CRS/CRSU service agreements in conjunction with the overall budget

Clinical Research/Trials Updates

Your IAF package for a new clinical research study or trial should include:

- Completed and signed CCA package (including SOMCT signature)
- Final Internal and Sponsor Study budget (we are actively working to get an updated template that will have a school signature)
- VCU Ancillary Pricing Documentation
- VCU CR and CT Billing Set-up form for VCUHS
- Protocol/synopsis or proposal submission
- Informed Consent document (Draft)
- VCU IAF Supplement
- Contract (for industry sponsor's)

Clinical Research/Trials Updates

NOTICE – CRS Notification issued May 15, 2014

Link to full notice on CCTR website:

http://www.cctr.vcu.edu/pdfs2/crs_charge_notification.pdf

This announcement relates to the charge structure associated with the utilization of Clinical Research Services resources. If your area utilizes CRS services, including the services and facilities of the CRS Unit on North 8, you should read this notification as it describes changes effecting the cost recovery model for CRS services.

This will be effective June 1, 2014

Please direct any questions related to this announcement to CCTR

Questions??



SOMPROPOSALS@vcu.edu

Proposal Submission Process

Pre-award questions

Proposal submission for SOM review

SOMRESADMIN@vcu.edu

All post award administration matters

Research Dashboard

SOMCT@vcu.edu

Clinical Research/Trial pre-study process

Clinical Research/Clinical Trial matters,
regardless of sponsor type:

Administration, operations, budgeting, billing compliance,
OnCore®

