PURPOSE

The purpose of this operating procedure is to clarify and define the roles of the Principal Investigator (PI), Department Administrator (DA), and the Research Administrator (RA), with regard to administratively and financially closing fixed price agreements.

VCU School of Medicine expenses on sponsored projects must comply with federal regulations, which are codified in a single guidance document known as the “Uniform Guidance” or 2 CFR 200 that must be used by all federal agencies. The Uniform Guidance (UG) provides standards to determine whether costs can be charged to federal grants and how those costs should be distributed between direct costs and facilities and administration (F&A) costs. These principles are rigorously applied to all federal grants and generally adhered to in administering non-federal awards. Each federal agency has or will issue more detailed guidelines as to how UG applies to its grants and cooperative agreements.

The standards established in the UG require that all sponsored project expenses must be (1) reasonable, (2) allocable to the project, (3) given consistent treatment, and (4) conform to any limitations or exclusions set forth in the UG or the award requirements.

Per Grants & Contracts policy, fixed price agreements closing with cash balances greater than $5,000 or greater than 10% of the budget (based on total cash received) require approval of the SOM Dean’s Office in order to transfer those balances to a department or investigator pool account. SOM Dean’s Office review and approval applies to all fixed price agreements, regardless of sponsor type.

INTRODUCTION

Grants and contracts for sponsored projects represent a contractual obligation between the grantor and the University for the performance of a specific activity through which the grantor, or sponsor, is entitled to receive some consideration or benefit. The contractual obligation is normally documented by a proposal and award combination, contract, or a written memorandum of agreement. The University assumes full legal responsibility for complying with all requirements imposed by the grantor or sponsor upon acceptance of grants and contracts for sponsored projects, including a requirement for a report of expenditures or a provision for an audit (refer to VCU’s policy Sponsored Programs Award Review, Negotiation, Acceptance and Notification). In turn, the School of Medicine must ensure its investigators and personnel are in compliance with all VCU and sponsor requirements for the administration of these sponsored programs.

Many fixed price agreements are also clinical trials or clinical research studies. Clinical studies that involve clinical visits, tests, or procedures and have complex sponsor billing requirements require a heightened level of attention to financially manage. These types of projects must be thoroughly reviewed at the time of closeout to ensure all financial obligations have been met and the sponsor has been invoiced for all items completed per the clinical study agreement.

Per VCU Grants & Contracts Accounting policy, departments may transfer the residual cash balance on indexes associated with fixed price agreements to a fixed price pool index to use these balances for other research expenses. Depending on the size of the residual balance, the SOM Dean’s Office and VCU Grants & Contracts Accounting require backup documentation and School/Department approval of the intent to pool the balance.
The School of Medicine is ultimately responsible for ensuring all necessary expenses have been applied and/or paid by the study and that the revenue due from the study sponsor has been invoiced and received.

**PROCEDURE**

*If the fixed price agreement is a clinical trial, the RA will*

Determine that the study is ready for financial closeout review to begin. Reasons may include:

- Study end date is within 30 days.
- Notification received from sponsor that the study will terminate
- Notification received from study team/administration the study will terminate

Verify the study status in OnCore and with the study team. The study should be closed to enrollment and no further subject visits are scheduled to occur.

Gather confirmation from the Clinical Trials (CT) Finance team that the study has been financially reconciled – all payments that are due to VCU based on subject activity and the clinical trial or sponsored agreement should have been invoiced prior to beginning the fixed price agreement closeout process. **The below procedures can be carried out while waiting for this confirmation.**

Work with the PI and DA to ensure that all applicable and appropriate expenses have been applied to the index:

- Salary and fringe benefits budgeted for all study team members (to include PI, CRC, Post-Award, Sub-PIs, etc) have been charged to the study according to the **per subject study activity that has occurred**.
- Salary and fringe benefits budgeted for all study team members (to include PI, CRC, Post-Award, Sub-PIs, etc) have been charged to the study for **all “invoiceable” items that have occurred and been reimbursed by the sponsor**.
- All anticipated ancillary service provider bills (VCUHS, MCVP, IDS, CRS, etc) that CT Finance has indicated as study billable have been paid from the study (Department to confirm).
- External subcontractor invoices/payments

**For all fixed price agreements, the RA will:**

*If the balance remaining is greater than 10% of total cash received or balance exceeds $5,000:* gather all of the required documentation for SOM Dean’s Office review:

- G&C Accounting Fixed Price Agreement Closeout Form (signed by PI and Dept Chair/designee)
- G&C Accounting Final Expenditure Report – “FER” (signed by PI)
- G&C Accounting 90 Day Notice filled out appropriately (signed by Dept FA, OSP, Dept Chair/designee, and PI)
- Narrative justification for the balance:
  - Narrative justification should include an explanation of why costs incurred were significantly under budget and the Department’s plans for using the pooled funds.
  - If the justification cites an error in the allocation of expenses, provide an explanation of why/how the error occurred and the corrective actions taken to prevent recurrence.
  - A narrative justification **signed** by the PI/Dept is **required** if you are requesting to pool the direct cost portion of a balance **over** 10% of cash received. The memo must clearly state that you are requesting an exception to pool a balance exceeding 10%.
- Copy of final VCU internal budget
- Copy of final approved sponsor budget
• A summary of individuals charged to the project and their roles, i.e. PI – Dr. Smith, $10,345, time period (start/end), etc. This information should be verifiable in Banner and/or the Effort Reporting System. Screenshots from Research Dashboard are acceptable as long as they are verifiable and supply all of the information requested.

• A summary of the number of patients enrolled, the number of patients that completed the study, the number of screen failures, etc. Any information that can be used to evaluate study activity is needed. **DO NOT include patient names or any other identifying information.** This information can be gathered from the OnCore system.

• Any additional memos, emails, clarification statements, etc. that would assist review or that were requested by G&C/OSP during closeout preparation.

Remember: the more complete and descriptive the supporting information, the more efficient the review process.

Email all required documentation to SOMRESADMIN@vcuhealth.org. The SOM Dean’s Office will review the request to pool the balance and gather SOM Dean’s Office and VP Health Sciences signatures. Signed documents will be returned to Department via email.

**RESPONSIBILITY**

**Principal Investigator (PI)** The PI is primarily responsible for:

• Reviewing and approving all final closeout documents and all final expenses.
• Providing a written request to pool a balance greater than 10% of cash received along with any required written justification for large unspent balances.

*For studies supported by the central SOM CT Finance team:*

**CT Financial Analyst** The CT Financial Analyst is primarily responsible for providing the following verifications to the RA:

• Verifying all anticipated clinical or ancillary service invoices (VCUHS, MCVP, IDS, CRS, etc.) have been received, verified, and sent to the department for payment.
• As applicable, ensuring all “invoiceable” items have been billed to the sponsor.
• As applicable, ensuring all payments from the sponsor have been received and reconciled according to study activity occurred.

**Research Administrator (RA)** The RA is primarily responsible for:

• Receiving all applicable confirmations from CT Finance staff regarding accounts payable and sponsor invoicing.
• Confirming all expenses have been applied to the study index: personnel and non-personnel expenses.
• Preparing the final financial reconciliation and reviewing it with the study PI to ensure personnel allocations and non-personnel expenses are reasonable.
• Preparing all VCU and SOM required close-out documentation.

*For studies NOT supported by the central SOM CT Finance team:*

**Research Administrator (RA) and other Department staff** are primarily responsible for completion of all activities identified above.