

October 6, 2017

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**Subject: *Moores Cancer Center Clinical Trials Office Review
Report 2016-81***

The final report for *Moores Cancer Center Clinical Trials Office*, Report 2016-81, is attached. We would like to thank all members of the department for their cooperation and assistance during the review.

Because we were able to reach agreement regarding management action plans in response to the audit recommendations, a formal response to the report is not requested. The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the management action plans.

UC wide policy requires that all draft reports be destroyed after the final report is issued. We also request that draft reports not be photocopied or otherwise redistributed.

David Meier
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Attachment

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AUDIT & MANAGEMENT ADVISORY SERVICES

Moore's Cancer Center – Clinical Trials Office
Report No. 2016-81
October 2017

FINAL REPORT

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ATTACHMENT A – Industry-Sponsored Clinical Trial Surplus/Deficit Funds

I. EXECUTIVE SUMMARY

Audit & Management Advisory Services (AMAS) has completed a review of the Moore's Cancer Center (MCC) Clinical Trials Office (CTO), in partnership with the Health Sciences Research Compliance Program (RCP), at the request of Health Sciences management. The overall objective of the coordinated AMAS and RCP review was to evaluate the CTO processes, including processes supporting clinical research billing, sponsor invoicing, recharge processing and financial management of CTO funds. AMAS evaluated the CTO recharge process, financial position and financial management of clinical trials, while RCP focused on the review of a sample of studies and sponsor billing and invoicing practices.

The results of our review, and management action plan to address issues noted, are summarized briefly below. We noted that in the latter stages of our review, the UCSD Vice Chancellor Chief Financial Officer / Health Sciences Chief Financial Officer requested the UCSD Controller, who also serves as the Health Sciences Financial Officer, engage with MCC leadership to coordinate on a number of financial matters. The Controller is providing ongoing guidance to MCC leadership to ensure that MCC CTO financial administration practices are consistent with University policy. The Controller's knowledge of established practices on other Campus and Health Sciences units can also be leveraged in this effort.

A. Recharge Model

The CTO administrative recharge in place at the initiation of our review was not implemented in the manner approved by the Campus Recharge Rate Review Committee (RRRC).

Management Action Plans:

1. The UCSD Controller, as the executive responsible for final approval of recharge rates, has approved the current recharge methodology retroactive to July 1, 2014.
2. The Financial Analysis Office (FAO), in conjunction with MCC and CTO leadership, will conduct a time study to evaluate costs and determine whether a modified recharge rate is necessary, to allow cost recovery of CTO operations (including covering prior deficits) in compliance with University policy.
3. CTO will submit any future revisions to recharge rates to the RRRC for formal campus approval, in compliance with University policy. MCC PIs will be timely informed if a new cost recovery mechanism is adopted.
4. On an annual basis, in conjunction with the budget process and based on results of the time study, CTO expenditures and revenue will be evaluated, adjusting the cost recovery model as needed to account for deficits or surpluses.

B. CTO Recharge Operations - Financial Management

Financial monitoring of CTO recharge indexes needed improvement to ensure that all expenditures were appropriate, related to CTO activities, and within budgetary limits.

Management Action Plans:

1. The deficit balance for one CTO recharge index, CCT1818, has been resolved as of August 31, 2016 and the index has been inactivated.

2. The CTO Finance Manager will coordinate with the Controller's Office and MCC Director of Finance Performance Management to develop an overdraft resolution plan for the remaining CTO recharge indexes in deficit, in accordance with the Campus Overdraft Policy.
3. The CTO Finance Manager will work with the MCC Director of Finance Performance Management to review CTO recharge index balances on a regular basis.
4. The CTO Finance Manager will monitor recharge index expenses on a monthly basis for appropriateness of payroll and other expenses. Charges unrelated to CTO operations will be transferred to appropriate fund sources.
5. The MCC Director of Finance Performance Management, CTO Administrative Director and CTO Finance Manager will conduct quarterly performance meetings to discuss CTO financial balances, invoicing accuracy and other issues as appropriate.

C. MCC Clinical Trials - CTO Fund Management and Accounts Receivable

Fund management could be improved to provide more effective oversight of financial balances, consistent reporting, and increased transparency for PIs with respect to study fund activity.

Management Action Plans:

1. The CTO Finance Manager will coordinate with the Controller's Office and MCC Director of Finance Performance Management to develop an overdraft resolution plan for the CTO study indexes in deficit, in accordance with the Campus Overdraft Policy.
2. The CTO Finance Manager will work with the MCC Director of Finance Performance Management to review CTO study index balances on a regular basis.
3. Final guidelines and implementation plan on PI fees has been endorsed by Health Sciences and MCC leadership and communicated to PIs.
4. The CTO Finance Manager is restructuring the Finance team to allow more time for designated staff to track accounts receivable and establish regular reporting to the Manager.
5. The CTO Finance Manager, in conjunction with the Controller and MCC Director of Finance Performance Management, will develop Standard Operating Procedures (SOPs) on fund management practices to clarify the responsibilities of CTO, PIs and Project Managers. Topics to be addressed include monthly financial review, reporting, cost transfers, study close-out procedures, and residual balances. Practice currently in place in other Health Sciences units could be leveraged to assist in this effort.
6. The CTO Finance Manager, in conjunction with the Controller and MCC Director of Finance Performance Management, will develop SOPs on A/R management including timelines for follow up, escalation, and reporting.
7. The MCC Director of Finance Performance Management, CTO Administrative Director and CTO Finance Manager will conduct quarterly performance meetings to discuss A/R status and clinical trial index balances as necessary.

Observations and related management action plans are described in greater detail in section V. of this report.

II. BACKGROUND

Audit & Management Advisory Services (AMAS) has completed a review of the Moore's Cancer Center (MCC) Clinical Trials Office (CTO), in partnership with the Health Sciences Research Compliance Program (RCP), at the request of Health Sciences management. This report summarizes the results of the AMAS portion of the review. RCP results will be communicated separately.

The MCC CTO is an academic support recharge unit which provides services to Principal Investigators (PIs) in MCC to run their clinical trials, with approximately 14 Project Managers, 21 Regulatory, 11 Consulting staff and 65 study coordinators. The CTO operation is headed by a Director (a faculty member and MCC Senior Deputy Center Director, Clinical Science), an Assistant Director (faculty member) and an Administrative Director. A CTO Finance Manager reports to the CTO Director and also has a dotted line reporting relationship to the MCC Director of Finance Performance Management. Other Regulatory and Consulting staff report to the Administrative Director whereas Project Managers report to designated PIs with a dotted line reporting to the Administrative Director. Project Managers prepare the clinical trial budgets, negotiate the budgets with the sponsor, file all internal paperwork, and assist in finalizing the clinical trial agreements. Regulatory staff submit the protocol to the UCSD Institutional Review Board (IRB) and any amendments after the study is approved. Once the contract has been finalized and the study initiated, Project Managers are responsible for overseeing the clinical trial from initiation to close-out, and supervising Study Coordinators. Consulting Services support the clinical trials through Velos reconciliation, financial management of CTO recharge and clinical trial indexes, sponsor billing, and accounts receivable management.

The CTO has approved recharge rates for their Project Managers, Regulatory Staffing, and Consulting Services, which were last revised effective Fiscal Year (FY)14-15. These recharge rates were approved by the UCSD Recharge Rate Review Committee (RRRC). Based on ledger activity, the MCC CTO received nearly \$3.5M in revenue in FY15-16.

Funding sources for the CTO consists of:

- Pre-established percentages of recharge revenue earned from clinical trial sponsor payments posted to the recharge operating index (index CCT1390, and previously CCT1818);
- A share of indirect cost (IDC) revenue recovered from sponsored research agreements (approximately 54% of IDC collected) posted to an indirect cost reserve index (CCT1817);
- UC San Diego Health (UCSDH) annual support of \$450K for National Cancer Institute (NCI) Cooperative Group clinical trials, and coverage for one full-time equivalent (FTE) staff dedicated towards Velos reconciliation, posted to index CCTCTOA. This index was primarily used to capture costs associated with Cooperative Group studies.

In addition, the MCC's NCI Cancer Center Support Grant funded a portion of salary and benefit expenses for designated CTO administration, in the amount of approximately \$300k per year.

CTO staff were paid from the above indexes centrally managed by CTO, with the exception of Study Coordinators, who are direct-charged to the research studies they support.

Recently, a CTO Governance Committee was created to provide strategic advisory and governance support to the CTO Director, to ensure alignment and achievement of critical success factors for long term growth and success of the CTO. The Committee is comprised of the CTO Director, MCC Director, UCSDH Chief Executive Officer, Cancer Services Chief Administrative Officer and, four MCC faculty members. Some of the Committee responsibilities include advising the CTO Director on strategies, policy development and sources/uses of funds; reviewing financial metrics and financial reporting of the CTO and; providing input to the Director regarding guiding principles, methodology and metrics for allocation of costs associated with staffing and other administrative resources for the CTO.

III. AUDIT OBJECTIVE, SCOPE, AND PROCEDURES

The overall objective of the coordinated AMAS and RCP review was to evaluate the CTO processes, including processes supporting clinical research billing, sponsor invoicing, recharge processing and financial management of CTO funds. AMAS evaluated the CTO recharge process, financial position and financial management of clinical trials, while RCP focused on the review of a sample of studies and sponsor billing and invoicing practices.

In order to achieve our objective, we performed the following:

- Reviewed applicable University of California (UC) and UCSD policy and guidance on recharges, overdrafts and sponsored projects administration;
- Discussed CTO recharge mechanism and financial support with:
 - CTO Director,
 - CTO Assistant Director,
 - CTO Administrative Director,
 - CTO Finance Managers (former and current),
 - CTO Finance Analysts and Billing Specialists;
- Evaluated the current recharge model for compliance with UC and UCSD policy;
- Evaluated total recharge income using approved recharge rates, and compared to actual recharge income;
- Discussed potential alternative recharge mechanisms for CTO with the Director of the Financial Analysis Office (FAO), who is a member of the Recharge Rate Review Committee;
- Discussed CTO Finance team roles in relation to fund management, deficit monitoring and PI communications with former and current Finance Managers and, MCC Director of Finance Performance Management;
- Evaluated deficits for CTO recharge indexes and CTO-managed clinical trial indexes;
- Reviewed a sample of payroll and supplies and expense charges on CTO recharge indexes;
- Analyzed costs for CTO recharge operations for FY15 and FY16;
- Tested the timeliness and accuracy of recharge billing and postings for a sample of invoices and overall postings to the ledger for FY15 and FY16;
- Reviewed accounts receivable management with Finance staff for a sample of invoices; and
- Interviewed five PIs that use CTO for management of their clinical trials to obtain feedback on CTO services and communication practices.

IV. CONCLUSION

Based on our review, we concluded that the CTO administrative recharge in place at the initiation of our review was not implemented in the manner approved by the RRRC. Rather than utilizing the hourly rates and methodology approved by the RRRC, CTO implemented the recharge to recover a percentage of revenue from industry sponsor payment of clinical services provided to participants of research studies. University policy requires that recharges be related to the cost of goods or services furnished and must provide for the recovery of actual costs. While the CTO Director indicated this analysis had been performed in the past to relate the percentage of industry sponsor revenue recharged to CTO costs, this information was not made available for our review. Therefore, we could not confirm that this practice was in strict compliance with policy. We noted that this mechanism did not appear to result in a higher aggregate recharge revenue for the CTO than what would have been earned using rates approved by the RRRC, therefore in the aggregate, studies were not overcharged for CTO services.

We noted that the CTO recharge did not fully recover operating costs for FY2016. Because the recharge mechanism was based on revenue rather than cost recovery, there is risk of increased deficit balances for the CTO in future. In addition, as of June 30, 2016, the CTO recharge indexes had an overall deficit balance of \$1.59M, primarily due to historical deficits in the program prior to FY15, and indexes in deficit needed resolution in accordance with Campus Overdraft Policy.

The CTO provides a valuable service to support the 270 currently active MCC clinical trials. Once fully staffed, CTO can be an effective resource to ensure MCC clinical trials are managed efficiently, ensuring appropriate fiscal oversight, and compliance with clinical research billing requirements. Since the cost of this operation is not fully funded centrally, it is appropriate to pass the costs of providing these services to the studies supported, and through to industry research sponsors. However based on our review, the current model should be reevaluated, and a more simplified funding model considered. If a methodology different than the approved version will be utilized, this should be resubmitted to the RRRC.

We also concluded that financial monitoring of CTO recharge indexes needed improvement to ensure that all expenditures were appropriate, related to CTO activities, and within budgetary limits. This includes the resolution of deficits in accounts related to CTO central administrative functions, as well as stricter oversight to ensure that all expenditures on CTO administrative indexes are related to CTO central operations. Our review identified \$70,449 charges that appeared unrelated to CTO operations which needed further evaluation.

We also concluded that fund management could be improved to provide more effective oversight of financial balances, consistent reporting, and increased transparency for PIs with respect to study fund activity. The CTO has been subject to high turnover, and the Administrative Director and Finance Manager positions were filled over the last few months. With these new hires, coordination between the CTO and MCC leadership has been strengthened. The Finance team hired more analysts to provide financial management services for the CTO and the Finance Manager is structuring the division of responsibilities within her team. However, reporting channels between the Finance team and the CTO Administrative Director could be further strengthened to improve administrative oversight.

V. OBSERVATIONS REQUIRING MANAGEMENT ACTION

A.	Recharge Model
<p>The recharge methodology in place at the initiation of our review was inconsistent with the approved recharge rate for the CTO. In addition, it was not clear how the adopted recharge model (recharging based on a percentage of industry sponsor payments) related to the operating costs of the CTO, as required by University Policy.</p>	
Risk Statement/Effect	
<p>Inability to break even on recharge costs can result in higher deficit balances for the CTO recharge operation in future.</p>	
Management Action Plans	
A.1	<p>The UCSD Controller, as the executive responsible for final approval of recharge rates, has approved the current recharge methodology retroactive to July 1, 2014.</p>
A.2	<p>The Financial Analysis Office (FAO), in conjunction with MCC and CTO leadership, will conduct a time study to evaluate costs and determine whether a modified recharge rate is necessary, to allow cost recovery of CTO operations (including covering prior deficits) in compliance with University policy.</p>
A.3	<p>CTO will submit any future revisions to recharge rates to the RRRC for formal campus approval, in compliance with University policy. MCC PIs will be timely informed if a new cost recovery mechanism is adopted.</p>
A.4	<p>On an annual basis, in conjunction with the budget process and based on results of the time study, CTO expenditures and revenue will be evaluated, adjusting the cost recovery model as needed to account for deficits or surpluses.</p>

A. Recharge Model – Detailed Discussion

Current Implementation

We noted that the current recharge methodology is inconsistent with the approved recharge rate for the CTO. In February 2015, a modification to the research rates for the CTO was submitted effective retroactively from July 1, 2014 and approved by the Recharge Rate Review Committee. The approved proposal established hourly recharge rates for Project Managers (\$59), Regulatory Staffing (\$54) and Consulting Services (\$54).

The current CTO recharge was not implemented consistent with the approval above. Instead, effective July 1, 2014, CTO calculated the recharge as a pre-determined percentage (%) of industry sponsor payments received (excluding overhead) applied as below:

- 0%: Pharmacy fees, PI fees, IRB fees (annual and start up);
- 20%: Patients visits, Patients variables (add-ons);
- 100%: Administrative fees, IRB protocol/amendments, adverse event and investigative new drug (IND) reporting.

The CTO Director informed that the reason the recharge rate was implemented in this manner was to reduce administrative burden that would have been required for staff to track actual hours spent on each study, to determine the actual costs on a per-study basis. Therefore, it was determined that applying a percentage of revenue would approximate the operating costs of the CTO, and would be simpler to implement.

However, it was not clear how this practice of recharging based on a percentage of revenue received (industry sponsor payments) related to the operating costs of the CTO. University policy (*Business and Finance Bulletin (BFB) A-47, Direct Costing Procedures*) states: "Recharges shall be related to the cost of goods or services furnished and must provide for the recovery of actual costs, including applicable depreciation. Prices shall be adjusted at least annually to eliminate any surpluses or deficits. Every effort should be made to ensure that year-end surpluses do not exceed one month of the recharging unit's activity." In addition, under Blink Guidance, Academic Support Activities FAQ: "Rates will be based on standard cost accounting principles...Rates must have an auditable basis."

The CTO Director stated that the 20% charge on sponsor clinical payments reflected the costs of running the CTO operation, based on calculations that were performed when the recharge was initiated. At that time the analysis was performed, the calculations indicated an even higher percentage - up to 40% - could be charged to reflect CTO costs. The 20% was selected because it was determined this amount could be recovered through industry sponsor budgets, and the gap was to be addressed with the IDC recovery and annual/initial administrative start up fee in sponsor budgets.

However, evidence of these calculations, and a basis for relating operating expenditures to a percentage of revenue, was not made available for our review. Without a clear basis in costs, the rates could be perceived as arbitrary, as there was not an "auditable basis" in cost for the implementation of the rates. Therefore, we could not confirm that this practice was in strict compliance with policy.

Impact to Study Budgets

We interviewed a sample of PIs, some of whom expressed that they were not timely informed of recharge methodology and were concerned on the impact of the 20% recharge on patient care costs charged to study budgets. Some expressed that the recharges to studies with higher-cost clinical procedures were disproportional to the actual amount of effort expended by CTO in administering their studies. Therefore, it was perceived that certain studies may be subsidizing CTO effort on other studies or initiatives. The current CTO time reporting structure did not require CTO staff to record time (hours) on each study. CTO leadership did not support a time reporting system as they felt it would create an administrative burden on staff who managed multiple trials, and could result in a negative view towards staff that support unfunded studies (such as cooperative group studies). However, this resulted in a lack of clarity regarding how staff time was actually spent. Therefore we could not analyze whether individuals studies were charged disproportionate to CTO effort.

To assess the impact of the current recharge implementation against the approved recharge mechanism (hourly rates), we performed an analysis to evaluate, in the aggregate, the recharge income received through the current method versus the revenue that would have been received had the approved model been implemented. We evaluated the actual overall recharge income received for the period July 1, 2015 through May 31, 2016 and compared it to the estimated recharge income that would have accrued if RRRC approved recharge rates had been implemented¹. Our results revealed that the RRRC approved rates would have yielded higher overall revenue (for the CTO in aggregate) than the actual recharge income under the current recharge model. Therefore, in the aggregate, studies were not overcharged by virtue of CTO using this model. However, the model as implemented may result in some studies with a higher cost study procedures taking a disproportionate share of the recharge that was not correlated with the level of effort expended by CTO staff for the study.

The CTO Director explained that since sponsor budgets are marked up for their recharge portion (20% of the cost), this is a moot issue as the CTO is merely flowing the recharge mark-up back to the CTO. In effect, the 20% markup on patient care costs represented a fully loaded rate of providing the service, including the administrative and compliance efforts that surround the activity. The recharge model was submitted to the RRRC in February 2015 and once it was approved, the CTO implemented the recharge using the percentage of sponsor revenue method. This was applied retroactively to all studies active as of July 1, 2014, therefore the 20% mark-up may not have been included in all study budgets active at that time.

CTO Operating Costs

Recharge operations should seek to break-even and provide for recovery of actual costs. We analyzed CTO recharge operation costs and revenue for CTO recharge indexes² for FY2015 and FY2016 and our results are presented in the table below. The current recharge model appears to recover costs over the two year period (FY15 and FY16), but does not account for deficits that were carried forward from years prior to FY15. The CTO recharge had an overall deficit balance of \$1.59M (sum of year-end balances for CCT1390, CCT1817, CCT1818 and CCTCTOA). However, \$935K (59%) of the total deficit related to deficits that were carried forward from years prior to FY15.

In addition, costs in FY16 have increased without a corresponding increase in revenue, which if continued will likely prevent cost recovery in future years. Payroll expenses in FY16 increased by 28% from FY15 with a 13% overall increase in other expenses (S&E, Equipment, Travel). The table below illustrates FY15 and FY16 revenue and expenditures for the CTO.

¹ The estimated recharge income was based on payroll costs and hours posted to recharge indexes (excluding CCTCTOA), but has not been adjusted for any payroll related errors that may exist within the indexes.

² Based on expanded budget summaries for CTO recharge indexes including: CCT1390, CCT1817, CCT1818, CCT1819, CCT1820. CCTCTOA was excluded as it is used for recording cooperative group support and expenses.

	FY14/15 ³ (\$)	FY15/16 ² (\$)	Total (\$)	Difference between FY (\$)	% Change
Revenue for the current FY⁴	3,471,806	3,447,419	6,919,226	(24,387)	-1%
Expenditures:					
Sub 0 Academic Salaries	29,386	39,894	69,280	10,508	36%
Sub 1 Staff Salaries	1,717,559	2,126,725	3,844,283	409,166	24%
Sub 2 General Assistance	106,275	104,245	210,520	(2,030)	-2%
Sub 6 Employee Benefits	919,668	1,129,016	2,048,684	209,349	23%
Adjustments from prior years that posted in FY15 or FY16	(52,441)	81,608	29,166	134,049	
<i>Adjusted Payroll Sub-Total</i>	<i>2,720,446</i>	<i>3,481,488</i>	<i>6,201,934</i>	<i>761,042</i>	<i>28%</i>
Sub 3 Supplies and expense	349,498	412,673	762,172	63,175	18%
Sub 4 Equipment	12,934	-	12,934	(12,934)	-100%
Sub 5 Travel	9,850	6,650	16,501	(3,200)	-32%
<i>Total other expenses</i>	<i>372,283</i>	<i>419,324</i>	<i>791,606</i>	<i>47,041</i>	<i>13%</i>
Total Expenditures	3,092,729	3,900,812	6,993,541	808,083	26%
Income/(deficit) for FY	379,077	(453,392)	(74,315)	(832,469)	-220%

Inability to break-even on recharge costs will result in increased deficit balances for the CTO recharge in future. A routine annual process for budgeting for CTO expenditures, applying or modifying a recharge rate based on those budget estimates, and adjusting the rate annually to account for changes in operating costs is needed to ensure that CTO operating expenditures are fully recovered.

The current model also creates a time lag for recording of recharge income since income was not recorded until sponsor payments are posted to the clinical trial index, with the recharge journal being processed in the following month. There may be time delays in recharge calculations due to late invoicing to sponsors, delayed payments from sponsors, unclaimed checks, or inability to apply payments to an invoice. This delayed recharge revenue from being posted to the recharge index, and also contributed to the overall deficit balance at any single point in time.

Consideration of Alternative Models

It appears that a reevaluation of the CTO recharge model is needed to consider whether a mark-up of patient care costs on industry-sponsored research budgets is the optimal model. A first step would be to confirm projected CTO operating expenditures for future periods, taking into account potentially unrelated expenditures (described in Finding B). Although a project-based time reporting structure

³ Amounts have been adjusted for timing differences [i.e. recharge revenue posting to CCT1390 - this relates to the month for which the recharge was calculated (not the month the recharge was posted to the index). In addition, any cost transfers identified for prior fiscal years have been adjusted.]

⁴ Revenue includes \$302K in revenue posted to CCT1818 and CCT1820 for FY15 that could potentially relate to income adjustments that were processed in FY15 for revenue in prior FYs.

was not considered feasible by CTO leadership, the CTO could benefit from conducting an assessment of how staff spend their time and establish a baseline from which to budget future costs and drive improvement efforts.

Financial modeling should be performed of alternative approaches to recover CTO costs. In this analysis, other revenue streams should be considered, such as the IDC recovery and sponsor administration fees. For example, under the current budgeting model, initial and annual CTO administrative fees were charged to sponsors and fully recharged to the CTO. For FY16, CTO revenue from IDC was \$811,371. Although precise reports on actual administrative fees recovered from sponsors were not available, we estimated initial fees to be approximately \$500,000⁵ for FY16 (the annual administrative fee was considered more problematic to recover from sponsors, therefore we could not reliably estimate this). Obtaining a thorough understanding of CTO costs and their recovery under the current model would provide clarity to the difference that needs to be funded, and help assess alternative funding models that will allow full cost recovery.

A range of cost recovery models could be considered, such as a recharge based on an hourly-rate structure, a fixed fee structure, a fee based on study enrollment, or a hybrid model. If it is determined that cost recovery can best be achieved through continuing the current approach of recovering a portion of costs through the sponsor administrative fee and marking up patient care costs in sponsor budgets, this method would need to be modeled to confirm the percentage charged has a basis in CTO operating costs. The Financial Analysis Office (FAO) is available to assist in evaluating and suggesting recharge methodologies that would conform with policy.

Any model selected by MCC, if different than the currently approved methodology, should be submitted to the RRRC for formal campus approval. The mechanism should be communicated to PIs with consideration of the impact to in-process studies. Expenses and revenue should be monitored closely. On an annual basis, CTO expenditures and recharge rates should be evaluated, adjusting as needed to account for deficits or surpluses.

Discussion with some of the faculty members, including some who were part of the CTO Governance Committee indicated lack of detailed reports on CTO recharge operations revenue and expenditures to enable informed advice on optimal strategies for CTO recharge mechanism and management of CTO deficit. CTO can achieve increased transparency in costs by providing periodic financial reports of the recharge and CTO operations through the established Governance Committee.

⁵ Estimated Initial Administrative fee = average amount in sponsor study budgets (excluding IDC) x new studies for FY2016 (obtained from Office of Clinical Trials Administration).

B. CTO Recharge Operations – Financial Management	
Financial monitoring of CTO recharge indexes needed improvement to ensure that all expenditures were appropriate, related to CTO activities, and within budgetary limits.	
Risk Statement/Effect	
Inadequate monitoring of recharge indexes can lead to: <ul style="list-style-type: none"> - inappropriate expenses being charged to the operations causing deficits or, - deficits not being timely resolved. 	
Management Action Plans	
B.1	The deficit balance for one CTO recharge index, CCT1818, has been resolved as of August 31, 2016 and the index has been inactivated.
B.2	The CTO Finance Manager will coordinate with the Controller’s Office and MCC Director of Finance Performance Management to develop an overdraft resolution plan for the remaining CTO recharge indexes in deficit, in accordance with the Campus Overdraft Policy.
B.3	The CTO Finance Manager will work with the MCC Director of Finance Performance Management to review CTO recharge index balances on a regular basis.
B.4	The CTO Finance Manager will monitor recharge index expenses on a monthly basis for appropriateness of payroll and other expenses. Charges unrelated to CTO operations will be transferred to appropriate fund sources.
B.5	The MCC Director of Finance Performance Management, CTO Administrative Director and CTO Finance Manager will conduct quarterly performance meetings to discuss CTO financial balances, invoicing accuracy and other issues as appropriate.

B. CTO Recharge Operations – Financial Management – Detailed Discussion

CTO Recharge Overdraft

We analyzed CTO account activity and balances, and noted that as of June 30, 2016, the CTO recharge had an overall deficit balance of \$1.59M (sum of year-end balances for CCT1390, CCT1817, CCT1818 and CCTCTOA). However, \$935K (59%) of the total deficit related to deficits that were carried forward from years prior to FY15. There was also delay in recognition of recharge revenue for FY16 for the three months from April through June 2016 of \$636K (40%) in the ledger which would have reduced the overall deficit. The Overdraft Policy in place at the time of our review required written plans to be submitted to the cognizant Vice Chancellor for resolution of overdraft balances above \$10,000 over 60 days in overdraft. However, a deficit reduction plan had not been filed for the two CTO recharge indexes in deficit: CCT1390 (\$1,926,575) and CCT1818 (\$450,248).

The Overdraft Policy was updated effective in February 2017. The new policy requires that overdrafts be routinely monitored at the level of the Department Chairs and Business Officers. Methods for

addressing overdrafts are determined by the type of fund source in overdraft. Specifically:

- For sponsored projects (i.e., extramurally funded research awards), a written action plan must be developed to eliminate the Overdraft when the Fund’s cumulative expenses exceed the authorized funding from the sponsor for longer than 30 days. It is the responsibility of the Department Chair and Department Business Officer to ensure that an overdraft resolution plan is in place.
- For Funds other than sponsored projects (such as the CTO administrative recharge accounts) a written action plans must be developed to eliminate Overdrafts larger than \$25,000 or five percent of the Fund’s fiscal year budget, whichever is more. Action plans are submitted to the Department Chair/Designee and Vice Chancellor/Dean for review and approval. These overdrafts should be eliminated within six months of approval of the written plan. Any longer period for resolution of an Overdraft must be approved by the appropriate Vice Chancellor or Dean.

Evaluation of Recharge Expenses

We also evaluated the expenditures on the CTO recharge indexes for FY2015 and FY2016 to evaluate relationship of these expenditures to CTO activity. University Policy (*BFB A-47, Direct Costing Procedures*) states that “generally, costs shall be charged directly to the account to which they pertain.” In addition, Blink Guidance for Self Supporting Activity states "Costs incurred and assigned to the activity must be essential to the purpose for which the activity was established. These direct costs, also known as operating costs, are defined as all readily identifiable costs associated with the furnishing of goods or services, except for incidental administrative support such as clerical and secretarial assistance or minimal supervisory assistance that is not significant in time or dollar value, benefiting a single period."

Our analysis of supply and expense charges on recharge indexes identified \$70,449 charges that appeared unrelated to CTO operations. The table below summarizes the charges by description. Some expenses may relate to charges that could be attributed to clinical trial indexes.

Description	\$ Amount
Publication expenses/article purchase fees	\$ 39,618.46
Bulk and investigational drug charges	\$ 12,292.00
Membership dues/fees (AACR/ASCO)	\$ 2,405.00
Visa fees for Project Scientist	\$ 2,050.00
Dry ice	\$ 4,836.88
Medical Supplies (Fisher Scientific)	\$ 9,246.41
Total	\$ 70,448.75

We also reviewed payroll costs for 25 employees charged to CTO recharge indexes. Three of the 25 employees were identified as study coordinators whose payroll costs (totaling \$58,252) should have been charged directly to study indexes. There was also one project scientist with salary costs totaling \$97,734 that had been paid from CTO recharge indexes, but her role at the CTO was unclear. The detail on the transactions above were provided to CTO for their review to determine whether the expenditures should be transferred to another fund source.

In a future-state recharge model where recharge income is based on cost recovery for expenditures charged to CTO indexes, it will be necessary to ensure that all expenditures on these indexes are related to CTO central operations, and should not be more appropriately charged directly to other study or clinical trial indexes.

Financial Oversight

The CTO Administrative Director position was filled in May 2016 to provide oversight over the Finance team and regulatory staff and a Finance Manager thereafter hired in late June 2016. While coordination between the Finance Manager and the MCC Director of Finance Performance Management appeared strong, we noted that there was minimal communication between the Finance team and Administrative Director on the financial status of the CTO. Developing regular reporting structure will allow the Director to be informed of CTO recharge fund balances to update the CTO Director as necessary, initiate corrective action or provide guidance to the Finance team on any finance-related issues.

C.	MCC Clinical Trials – CTO Fund Management and Accounts Receivable
CTO fund management of MCC clinical trials funds could be improved to provide more effective oversight of financial balances, consistent reporting, and increased transparency for PIs with respect to study fund activity. In addition, accounts receivable (A/R) monitoring could be improved to ensure timely receipt of sponsor payments.	
Risk Statement/Effect	
Lack of clinical trial fund management and reporting increases the risk of inappropriate charges on funds and may result in funds going in deficit. Timely receipt of sponsor payments is critical to avoid clinical trial indexes from going into overdraft.	
Management Action Plans	
C.1	The CTO Finance Manager will coordinate with the Controller’s Office and MCC Director of Finance Performance Management to develop an overdraft resolution plan for the CTO study indexes in deficit, in accordance with the Campus Overdraft Policy.
C.2	The CTO Finance Manager will work with the MCC Director of Finance Performance Management to review CTO study index balances on a regular basis.
C.3	Final guidelines and implementation plan on PI fees has been endorsed by Health Sciences and MCC leadership and communicated to PIs.
C.4	The CTO Finance Manager is restructuring the Finance team to allow more time for designated staff to track accounts receivable and establish regular reporting to the Manager.
C.5	The CTO Finance Manager, in conjunction with the Controller and MCC Director of Finance Performance Management, will develop Standard Operating Procedures (SOPs) on fund management practices to clarify the responsibilities of CTO, PIs and Project Managers. Topics to

	be addressed include monthly financial review, reporting, cost transfers, study close-out procedures, and residual balances. Practice currently in place in other Health Sciences units could be leveraged to assist in this effort.
C.6	The CTO Finance Manager, in conjunction with the Controller and MCC Director of Finance Performance Management, will develop SOPs on A/R management including timelines for follow up, escalation, and reporting.
C.7	The MCC Director of Finance Performance Management, CTO Administrative Director and CTO Finance Manager will conduct quarterly performance meetings to discuss A/R status and clinical trial index balances as necessary.

C. MCC Clinical Trials - CTO Fund Management and Accounts Receivable – Detailed Discussion

Clinical Trial Deficits and Fund Management

University Policy (*Policy and Procedure Manual (PPM) 150-36, Responsibilities of Principal Investigators for the Administration of Awards*) states that:” The person(s) named in an award of a contract or grant accepted by the University as the principal investigator, manager or director has primary responsibility for adherence to the terms and conditions of the award and for ensuring that expenditures made are appropriate, allowable, and within budgetary limitation of the contract or grant.”

Effective fund management is essential to ensure that PIs are informed of financial account balances, and any deficit conditions. However, we noted that the fund management responsibilities of the CTO for clinical trials were not well defined and documented. We were informed that the CTO provided monthly reports to PIs on their awards which provided a summary of their awards, status, balances, outstanding amounts and PI fees distribution. However, expenditure breakdowns and projections were not presented which would assist in the evaluation of study costs for appropriateness and avoid costs from exceeding the study budget. Further, active monthly review of study costs was not performed by CTO, primarily due to staffing constraints. Monthly review would help identify any expenditures that may be unrelated to the study or potentially mischarged on a more timely basis, rather than waiting until a deficit condition exists or the study is being closed out. There were no documented procedures for resolution of potentially mischarged expenditures, which would typically involve communication with the PI and cost transfers to a more appropriate fund source, or study close-out procedures.

We also reviewed account balances for CTO-managed clinical trial index balances to evaluate the financial status of these accounts. Per Campus Overdraft Policy, the “PI named in the award is the primary person responsible for financial management and the control of project funds in accordance with University and sponsor policies and procedures. Thus, the Principal Investigator is accountable for ensuring that project expenditures do not exceed project budget allocations thereby avoiding a fund overdraft.”

We noted that as of July 31, 2016 identified 129 indexes with a deficit balance totaling \$2,731,184. Forty-nine (49) of these accounts with a total deficit balance of \$2,399,164 have been in overdraft for over 60 days and deficit balances above \$10K and required a written plan per Campus Overdraft Policy.

During our review, we also heard concerns regarding residual balances which may remain after completion of a study. Some PIs felt there was a lack of clarity as to what balances remain at the conclusion of a study, and/or restrictions on how these funds may be used. Residual balances after completion of a study represent unrestricted funds that can be spent either for research, administration or instruction. General Accounting Office has developed a process to transfer residual study balances to PI-specific index(es) in a Clinical Trial Reserve Fund (or alternatively transfer within the clinical trial fund through a budget adjustment journal) (**Attachment A**). Historically, campus practice has been to reallocate residual balances as unrestricted funds for the PI. This is consistent with the principle that PIs are the primary individual responsible for the financial aspects of the study, therefore surpluses can be reasonably transferred for their discretionary use. There were no documented procedures or basis for an alternate model within CTO.

PI, Project Managers and CTO responsibilities, approval procedures and communication practices should be documented to clarify their role in fund management of clinical trials. The CTO should also work with the PIs to manage overdraft conditions and any cost transfers to be processed to resolve the overdraft or inappropriate expenditures should be communicated to the PI. Documenting fund management responsibilities including cost transfers, study close-out and residual account procedures would help clarify CTO and PI role and expectations.

Accounts Receivable Management

We also evaluated CTO Finance team procedures for oversight of accounts receivable. Our analysis of open sponsor invoices as of August 16, 2016 identified \$8.1M in accounts receivable, of which \$2.5M (561 invoices) are over 120 days overdue. \$904K of the \$2.5M were identified as holdbacks⁶, which are settled at study close-out. (a 10-20% of payments held by sponsor to be settled at study close-out). Under the current process, the Finance staff followed up on open invoices, but the frequency of follow ups and documentation maintained was not defined. The Finance Manager did not appear to play an active role in monitoring of overdue invoices and take action and escalate problem invoices if needed.

⁶ A certain percentage of sponsor payment (usually within 10 – 20%) is held by sponsor

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INDUSTRY SPONSORED CLINICAL TRIALS SURPLUS/DEFICIT FUNDS

When an Industry sponsored clinical trial is completed, there is typically a surplus or deficit ending balance. UC San Diego General Accounting has developed a process that will allow UC San Diego Departments to easily transfer the clinical trial balance to a Clinical Trials Reserve fund. Funds in the Clinical Trials Reserve fund are unrestricted and may be spent in the same manner as surpluses currently residing in the Clinical Trials fund 79600A.

Instructions:

1. The surplus balance in the Clinical Trial fund 79600A are treated as "excess differential income." This means that no additional overhead will be assessed when the Clinical Trial funds are transferred to the Clinical Trials Reserve fund 75014A.
2. Funds in the Clinical Trials Reserve fund are unrestricted and can be spent for either Research or for Administration/Instruction.
3. For the first transfer to Clinical Trials Reserve fund, the Department must request an index be set up through General Accounting. The Department will need to provide the Investigator's organization and program number. If the Department does not specify a program number, the index will be set up in program number 440000 (Research). Please use separate indexes for Instruction (program number 400000) and Research (program number 440000).
4. The Researcher may have more than one index in the Clinical Trials Reserve fund. After the first index is set up by General Accounting, the Department may set up additional indexes in IFIS using the GA INDEXPY screen.
5. Departments will be responsible for performing their own entry to transfer the balance from the Clinical Trial fund to the Clinical Trials Reserve fund.
6. The transfers must be done by a Financial/Budget Entry (Rule Class FB08) and using the transfer (account) code 720705. This unique transfer (account) code will allow the charges to "stand out" on both the individual clinical trial index and in the Clinical Trials Reserve fund. This will assist the Department in tracking of the transfers.
7. The Department may transfer balances from one organization number in the Clinical Trials fund to a different organization number in the Clinical Trials Reserve fund.
8. Once the funds from the Clinical Trial fund/index have been transferred, the Department should align the subs in the clinical trial index to zero and close the index. If all subs are not at a zero balance, the index will be re-activated on July 1, and the sub balances will be carried forward.
9. The Clinical Trials Reserve fund earns stip. The stip will be handled in the same manner as the Clinical Trial fund.
10. As with indexes in the Clinical Trial fund, it is incumbent on the Researcher and their respective Department to ensure that their index(s) in Clinical Trials Reserve fund 75014A do not become overdrawn.

General Accounting also established a second option to transfer surplus/deficit clinical trial balances within the Clinical Trials fund. This can be accomplished through a Budget Adjustment Journal (Rule Class BE13) using account code 680000.

For additional information contact General Accounting through BFS support or visit the [General Accounting blink page](#).

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