

**UNIVERSITY OF CALIFORNIA, IRVINE  
ADMINISTRATIVE AND BUSINESS SERVICES  
INTERNAL AUDIT SERVICES**

**CHAO FAMILY COMPREHENSIVE CANCER CENTER  
Report No. I2013-207**

**May 29, 2013**

Prepared by:  
Loran Lerma  
Senior Auditor

Reviewed by:  
Mike Bathke  
Interim Director

May 29, 2013

**SHELDON GREENFIELD  
INTERIM DIRECTOR  
CHAO FAMILY COMPREHENSIVE CANCER CENTER**

**Re: Chao Family Comprehensive Cancer Center  
Report No. I2013-207**

Internal Audit Services has completed the review of the Chao Family Comprehensive Cancer Center and the final report is attached.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.



Mike Bathke  
Interim Director  
UC Irvine Internal Audit Services

Attachment

C: Audit Committee  
Ralph Clayman, Dean, School of Medicine  
Jacqueline Orozco, Director of Finance and Operations, Cancer Center  
Ginger Osman, Chief Financial Officer, School of Medicine

**CHAO FAMILY COMPREHENSIVE CANCER CENTER**  
**Report No. I2013-207**

**I. MANAGEMENT SUMMARY**

In accordance with the fiscal year (FY) 2012-2013 audit plan, Internal Audit Services (IAS) reviewed operational, financial and compliance activities, and other business operations of the Chao Family Comprehensive Cancer Center (CFCCC) of the University of California (UC), Irvine, School of Medicine (SOM). The CFCCC has a dual reporting relationship with the UC Irvine Medical Center (Medical Center) for clinical operations and the SOM for research operations. Business risks and control concerns were identified. Specifically, the following issues were noted.

**Study/Fund Management - Principal Investigator (PI) Reports** – The CFCCC does not consistently prepare study or fund management reports for the active and closed studies or sponsored projects and on a timely basis. Details are discussed in section V.1.

**Closeout of Clinical Trial Funds** – Several clinical trial studies within the CFCCC have been closed and the fund balances have been transferred to a CFCCC sales and services account/fund instead going to the related PI's accounts/funds. Details are discussed in section V.2.

**OnCore Clinical Trial Data Management System** – Recharging for patient data management and research procedure costs are not performed on a consistent and timely basis. The CFCCC installed a clinical trial data management system in 2009. System users received training and are currently using the system for patient study and regulatory compliance administration (Phase I). However, the CFCCC is not fully utilizing the functionality of the information system that includes implementing and using the study calendar builder as well as integrated financial reporting and study specific case reports. Details are discussed in section V.3.

**Purchase Requisition Documentation and Authorization** – Documentation and authorization of purchase requisitions need improvement. IAS reviewed expenditures charged to contracts and grants, and other institutional commitments/ongoing CFCCC obligations and found that some purchase requisitions were either missing or did not have authorized signature approval. Details are discussed in section V.4.

**Cash Handling/Physical Security** - The CFCCC safe is not in compliance with University cash handling requirements. Details are discussed in section V.5.

**CHAO FAMILY COMPREHENSIVE CANCER CENTER**  
**Report No. I2013-207**

**II. BACKGROUND**

The CFCCC was established in 1989 as a University-based Cancer Center. In 1994, it became a National Cancer Institute (NCI) designated Cancer Center, and it achieved NCI Comprehensive Cancer Center status in 1997. The CFCCC is Orange County's only NCI-designated Comprehensive Cancer Center, operating fully integrated cancer research, prevention, diagnostic, treatment, and rehabilitation programs.

Major clinical research efforts at the CFCCC focus on colon, liver, oral, pancreatic, melanoma/skin, women's cancers, prostate, and, cancer prevention studies and activities, in both Phase II and Phase III clinical trials. The CFCCC is one of only six institutes in the country chosen by the NCI to lead a chemoprevention consortium. This novel approach aims to accelerate the development of safe and effective cancer-prevention drugs through active collaboration across a network of research institutions.

Funding for research at the CFCCC comes from the NCI, the National Institutes of Health (NIH) and other public agencies, in addition to a variety of private sources.

**III. SCOPE AND OBJECTIVES**

The scope of this audit was to review the internal controls for key business operations, financial information, and compliance in the CFCCC from July 2011 to present. The review focused on the SOM CFCCC finance and research operations.

IAS established the following audit objectives:

1. Evaluate whether there are adequate controls over budgeting and accounting and verify whether ledgers are reviewed and reconciled in a timely manner;
2. Determine whether CFCCC is complying with the policies and procedures related to payroll processing and whether adequate processes and controls exist over vacation usage, approval, and reporting;
3. Verify that CFCCC related expenditures are properly authorized and processed in accordance with University policies and procedures as well as federal contract and grant costing guidelines;
4. Verify whether the required general, confidential, payroll, and medical documents are properly maintained and filed in personnel records;
5. Verify whether clinical research operations including patient data management, cost accruals, budgeting, financial commitments/expenditures, recharges, cost

**CHAO FAMILY COMPREHENSIVE CANCER CENTER**  
**Report No. I2013-207**

- reimbursement billings and receivables, are monitored, reported, and managed effectively in accordance with policy and terms and conditions;
6. Review cash handling procedures to determine whether evidence of controls exists and that assets are properly safeguarded;
  7. Review equipment inventory tracking procedures and determine whether they are in compliance with policy; and
  8. Determine whether gift donations administered through the CFCCC are processed according to gift policy.

**IV. CONCLUSION**

In general, internal controls and processes in CFCCC appear to be functioning as intended. However, business risks and control concerns relating to study/fund management reporting, clinical trial closeout procedures, clinical trial data management information system recharging, purchase requisition and approvals and cash handling/physical security need improvement.

Observation details and recommendations were discussed with management, who formulated action plans to address the issues. These details are presented below.

**V. OBSERVATIONS AND MANAGEMENT ACTION PLANS**

**1. Study/Fund Management (PI) Reports**

**Observation**

The CFCCC does not consistently prepare study or fund management reports for all active studies or sponsored research projects on a timely basis. PI reports are an essential fund management tool and the PI is ultimately responsible for the study progress and how the funds are used. A lack of effective reporting increases the risk that studies or sponsored project technical progress and financial commitments/expenditures may not be monitored and managed effectively which is necessary to account or plan for program changes or budget variances (technical scope changes, budget cuts, cost reductions etc.).

**Management Action Plan**

A PI report template has been developed that is being used for simple awards as well as more complex clinical trial patient participation awards. Several PI

**CHAO FAMILY COMPREHENSIVE CANCER CENTER**  
**Report No. I2013-207**

reports have already been generated and presented to the PIs during the course of the audit. The remaining reports will be generated and presented to the PI's by the end of May 2013. Thereafter, PI reports will be generated/presented quarterly unless the PI requests differently.

**2. Closeout of Clinical Trial Funds**

**Observation**

Several clinical trial studies within the CFCCC have been closed and the unexpended fund balances (carryover funds) have been transferred to a CFCCC sales and services account/fund instead being made available to the related PI's accounts/funds. Since PIs are normally paid for their effort at the end of the study, unexpended funds should to be allocated to PIs to pay for their work as specified in the award budget. IAS identified the following study amounts that were closed to the CFCCC carryover account:

FY 2012-2013 (July 2012 - February 2013)	\$47,558
FY 2011-2012	\$19,904
FY 2010-2011	<u>\$92,564</u>
Total	\$160,026

The Director of Finance Operations stated that she is behind in her fund closeout and carryover processing. She is working to catch up on the outstanding PI reports and will make the carryover funds available to the PIs as they are closed out.

**Management Action Plan**

During the course of the audit, the Director of Finance Operations produced PI reports for \$26,182 of \$47,558 of carryover funds for this fiscal year. The remaining reports were generated and presented to the PIs in May 2013 and the unexpected funds were allocated to the PIs. In the future, the PI reports mentioned in the Study/Fund Management Reports observation above will include detail for award closeout/carryover funds. In addition, PIs will have the option to leave the unexpended funds in CFCCC or have them transferred to their home department.

**3. OnCore Clinical Trial Data Management System**

**Observation**

Recharging for patient data management and research procedure costs are not performed on a consistent and timely basis. Data management activities are

**CHAO FAMILY COMPREHENSIVE CANCER CENTER**  
**Report No. I2013-207**

performed within the CFCCC and are accrued on a monthly basis, however, the costs are not charged to a study for at least 12 weeks or more. Recharging expenses on a timelier basis will allow the CFCCC to recover research costs already incurred and provide a more accurate accounting of the clinical trial financial reporting and technical progress.

The CFCCC installed a clinical trial data management system (CTMS) in 2009. System users received training and are currently using the system for patient study and regulatory compliance administration (Phase I). However, the CFCCC is not fully utilizing the functionality of the information system such as use of the patient study calendar, case report forms, protocol budgeting, and developing customized/automated reports. Use of these additional components will facilitate decision making by automating much of the recharge review process and sponsor invoicing. This should make a more efficient, timely, and accurate clinical trial data management monitoring and reporting processes.

**Management Action Plan**

Recharges will continue to be completed on a monthly basis for up-front and invoiced items. Payments are due from sponsors based on completion of cycles or milestones. Recharging study management on a monthly basis would not be cost effective under the current patient study circumstances without the benefit of an automated study review application (OnCore).

Until the OnCore financial module is fully implemented, recharges for data management based on patient participation milestones will be completed at a minimum on a quarterly basis unless nearing the end of the study.

After completing Phase I of the CFCCC CTMS implementation plan in 2010 our Programmer Informatics team was reduced from three to zero, which greatly affected our ability to fully implement Phases II and III. CFCCC is still in Phase II of the original CTMS OnCore implementation and has yet to implement study calendars and electronic case report forms. Phase II was planned to include charge master, patient study calendar, and electronic case report forms. Phase III was planned to include financial functionalities, including protocol budgeting, sponsor invoicing, patient billing, integration with the ADT/registration, laboratory, clinical/research data warehouse, and Biospecimen Management System.

CFCCC now has a provisional position included in their budget to the SOM for an Informatics Project Manager for informatics and operational decision support, custom reporting and data quality. The critical need for recruitment of this position in addition to a calendar builder was presented to our external auditors. CFCCC management will continue to work with SOM to fill these positions. A

**CHAO FAMILY COMPREHENSIVE CANCER CENTER**  
**Report No. I2013-207**

programmer, calendar builder, and ideally an additional data manager would facilitate increased use of the CTMS and implementation of Phase II and Phase III, which would offer improved functionality and efficiencies for patient participation as well as financial reporting, billing, and collections. Implementation will be started by September 30, 2013.

**4. Purchase Requisition Documentation and Authorization**

**Observation**

IAS reviewed 15 expenditures charged to five federal awards for compliance with federal guidelines and University policy. Three of the 15 expenditures (20 percent) lacked approved purchase requisitions to support the purchases. In addition, IAS reviewed 18 other expenditures and found that six (33 percent) purchase requisitions were either missing or did not have authorized signature approvals.

Expenditures should have complete and accurate documentation on file supporting the expense to ensure compliance with federal guidelines and University policy.

**Management Action Plan**

During the audit, CFCCC financial management has implemented an electronic review and signature/authorization process using Echosign for their requisition process as approved by the SOM and used by other SOM departments. CFCCC is now in their second month of use of the electronic review process and are now able to store items electronically as a PDF including the e-mail request and the CFCCC requisition (fashioned after the UC Irvine purchase order template).

CFCCC financial management has spoken with PIs, staff, and laboratory managers to emphasize the need for accurate and complete documentation of appropriate request, review, authorization, order, delivery and reconciliation of items to the correct account and fund.

**5. Physical Security of Cash**

**Background**

University policy requires cash to be stored in locked and fire resistant receptacles or safes. The required type of receptacle or safe is based on the cash limits outlined in University policy.

**CHAO FAMILY COMPREHENSIVE CANCER CENTER**  
**Report No. I2013-207**

**Observation**

IAS reviewed the CFCCC cash handling/physical security procedures and noted that the cash on hand was not properly secured in accordance with University policy. The cash on hand, used for human subject payments and donor gift funds wishing to give a money gift to cancer patients to be used to cover living expenses while the patient is receiving cancer treatment, exceeded the cash limit of the safe being used.

Failure to comply with University cash handling requirements may jeopardize the University's liability coverage and could result in a financial loss to the University.

**Management Action Plan**

With advice from the Cashier's Office, a new safe has been ordered to be in compliance with University policy. The plan is for the safe to be in place by the end of June 2013.