

April 30, 2019

ANDERS DALE
Director, Center for Translational Imaging and Precision Medicine
0841

**Subject: Center for Translational Imaging and Precision Medicine (CTIPM)
 Report 2019-17**

The final report for Center for Translational Imaging and Precision Medicine (CTIPM) Report 2019-17, 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
Director
Audit & Management Advisory Services

Attachment

cc: David Brenner
 Jim Brewer
 Judy Bruner
 Alex Bustamante
 Steven Garfin
 Gene Hasegawa
 Dave Kimber
 Alexander Norbash
 Pierre Ouillet
 Cheryl Ross
 Eric Wilson

UC San Diego

AUDIT & MANAGEMENT ADVISORY SERVICES

Center for Translational Imaging and Precision Medicine (CTIPM)
Report No. 2019-17
April 2019

FINAL REPORT

Performed By:

Tessa Melendez, Senior Auditor
Christa Perkins, Associate Director

Approved By:

David Meier, Director

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I. EXECUTIVE SUMMARY

Audit & Management Advisory Services (AMAS) has completed a review of the Center for Translational Imaging and Precision Medicine (CTIPM) as part of the approved audit plan for Fiscal Year 2018-19. The objective of our review was to perform an overall assessment of CTIPM's administrative internal control environment, compliance with University policies and procedures, and effectiveness of operations. Focus was placed on processes for separately accounting for research and clinical procedures.

We concluded that CTIPM internal controls provided reasonable assurance that operations were effective and in compliance with University policies and procedures. The unit had established policies governing the recharge use of its machines, and recharge activities were generally operated on a break-even basis in accordance with policy, based on financial balances. For the two machines that were used for both clinical and research purposes, procedures were in place to ensure that scans were appropriately classified as research or clinical in the Epic electronic health record, to enable downstream billing through the appropriate channel.

However, we noted that recharge procedures could be enhanced to ensure accurate and more consistent billing. We also noted that oversight of the GE cosigned MRI machine could be improved to ensure the terms of the Master Agreement are met and use of the machine is in accordance with Individual Study Agreements. Management Action Plans to address these observations are summarized below.

A. Recharge Billings

Management has implemented and will document a quality assurance process to ensure monthly billings are reviewed and confirmed via final schedule details to ensure all scans are accounted for.

B. Recharge Rates

CTIPM will ensure that users are charged only at approved recharge rates and will document instances of any offsets. If any revisions to recharge rates are needed, these should be submitted to the Recharge Rate and Review Committee (RRRC) for formal campus approval, in compliance with University policy.

C. GE Cosigned Keck Machine

1. CTIPM will provide enhanced oversight of the Keck machine to ensure all use is in accordance with an Individual Study Agreement, and will work with GE to ensure UCSD is aware of all studies approved for use.
2. Usage reports will be submitted timely, in accordance with the terms of the Master Agreement.

Management agreed to all corrective actions recommended to address risks identified in these areas. Observations and related management corrective actions are described in greater detail in section V. of this report.

II. BACKGROUND

Audit & Management Advisory Services (AMAS) has completed a review of the Center for Translational Imaging and Precision Medicine (CTIPM) as part of the approved audit plan for Fiscal Year 2018-19. This report summarizes the results of our review.

CTIPM is a unique organizational unit which provides medical imaging and analysis for both clinical and research purposes. Established in 2015, CTIPM brings together physicians from multiple University of California San Diego (UCSD) departments, including Radiology, Neurosciences, Psychiatry, Neurosurgery, Urology, Radiation Oncology, and Medicine. CTIPM's mission is to "develop next-generation technologies in medical imaging and analysis, test their efficacy for clinical practice, and make them available to physicians and their patients." To support this mission, CTIPM houses three magnetic resonance imaging (MRI) machines at three separate campus sites: the W.M Keck Building (Keck), the Altman Clinical and Translational Research Institute (ACTRI), and next to the Radiation Oncology PET/CT Center (ROPCC).

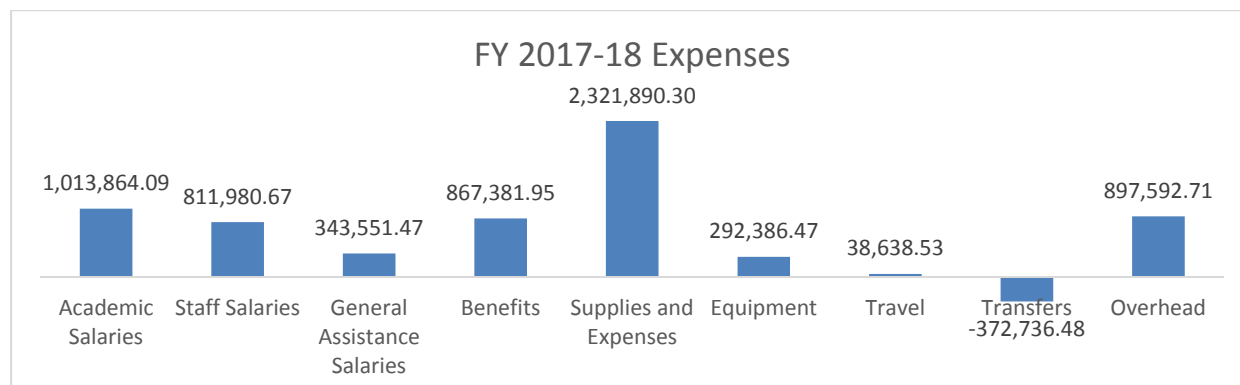
The ACTRI and ROPCC sites provide both clinical and research scans. Clinical operations as well as overflow and downtime coverage for the UCSD Health System usage of the ACTRI and ROPCC MRI machines are governed by a Memorandum of Understanding among the UCSD Medical Center, CTIPM, and UCSD School of Medicine, Department of Radiology.

The Keck MRI machine is strictly used for approved research studies in accordance with a five¹ year Comprehensive Research Agreement ("Master Agreement") between General Electric Company (GE) and the Regents of the University of California. The Master Agreement defines a program where individual studies seeking support under the agreement submit a proposal for GE approval which outlines the requested support, either financial or device use. An Individual Study Agreement is then executed which defines the study plan and support provided, which is subject to the terms of the Master Agreement. Twenty-four Individual Study Agreements have been issued under the Master Agreement. The Office of Contracts and Grants Administration (OCGA) assists in negotiating the statement of work elements for the Individual Study Agreements, including intellectual property and publication rights, after the plan and budgets have been successfully negotiated between the Principal Investigator (PI) and GE.

CTIPM is led by a Director, who has dual appointments as a Professor in the Departments of Neurosciences and Radiology, and has its own support team, including an Administrative Director/Management Service Officer and Clinical Operations Director. However, it is also supported by the Department of Radiology's business office. Clinical expenses are billed through a third party, while research-related scans are billed monthly via the recharge process.

Fiscal Year 2017-18 financial expenses at CTIPM totaled \$6.2 million with \$1 million in Recharges and nearly \$2 million in Revenue. The majority of expenses were comprised of Supplies and Expenses of \$2.3 million and total Salaries and Benefits of \$3 million:

¹ Currently in effect through February 2020.



III. AUDIT OBJECTIVE, SCOPE, AND PROCEDURES

The objective of our review was to perform an overall assessment of CTIPM's administrative internal control environment, compliance with University policies and procedures, and effectiveness of operations. Focus was placed on processes for separately accounting for research and clinical procedures. In order to achieve our objective, we performed the following:

- Reviewed:
 - Memorandum of Understanding;
 - Master Agreement with GE;
 - Budgets for Fiscal Years 2016-17 and 2017-18;
 - CTIPM recharge rate request and published rates;
 - Financial reports; and
 - CTIPM policies and procedures for using MRI machines,
- Reviewed University policies including, but not limited to:
 - UC Accounting Manual;
 - UC Business and Finance Bulletin (BFB) A-47: Direct Costing Procedures;
 - UC BFB A-56: Academic Support Unit Costing and Billing Guidelines; and
- Interviewed management and key personnel to discuss business processes, including the following:
 - Administrative Director, CTIPM;
 - Senior MRI Technician, Radiology;
 - Hospital Assistant, Radiology;
 - Assistant Project Scientist, Radiology;
 - Administrative Analyst, Research Service Core;
 - Principal Contract Officer, OCGA; and
 - Associate Director, OCGA,
- Evaluated:
 - Recharge rate balances at year-end to determine whether they were within allowable amounts;
 - Business process controls utilizing internal control questionnaires and segregation of duties matrices; and

- Clinical studies recharged on the GE cosigned MRI machine to determine if they had been approved via Individual Study Agreements,
- Reviewed:
 - Medical records to confirm billings were appropriately classified as research or clinical;
 - Submitted usage reports to determine if the terms of the Master Agreement with GE were being met, and
- Selected a sample of one month of recharges to verify the index and amount charged were accurate.

IV. CONCLUSION

Based on our review, we concluded that CTIPM internal controls provided reasonable assurance that operations were effective and in compliance with University policies and procedures. The unit had established policies governing the recharge use of its machines, and recharge activities were generally operated on a break-even basis in accordance with policy, based on financial balances. For the two machines that were used for both clinical and research purposes, procedures were in place to ensure that scans were appropriately classified as research or clinical in the Epic electronic health record, to enable downstream billing through the appropriate channel.

However, we noted that recharge procedures could be enhanced to ensure accurate and more consistent billing. We noted two instances in June 2018 when scans were not recharged and five scans billed in the same month that we could not confirm via calendar bookings. Additionally, recharge rates for analysis for two studies did not agree with approved rates, and we were unable to determine the basis for the rates.

We also noted that oversight of the GE cosigned MRI machine at Keck could be improved to ensure the terms of the Master Agreement are met and use of the machine is in accordance with Individual Study Agreements. Usage of the GE cosigned MRI machine at Keck is limited to those studies with Individual Study Agreements. However, we were unable to verify all scan usage on the Keck machine was associated with Individual Study Agreements. Additionally, according to the terms of the Master Agreement with GE, quarterly use reports are to be submitted. Our review disclosed only one report had been submitted since the execution date of the contract, February 20, 2015.

These opportunities for improvement are discussed further in the balance of this report.

V. OBSERVATIONS REQUIRING MANAGEMENT ACTION

A.	Recharge Billings
Recharge billings did not fully reconcile to the device schedules. Monthly recharge billings did not include two scans listed on the schedule and included five scans that could not be accounted for on schedules.	

Risk Statement/Effect	
Ineffective billing processes can lead to inappropriate expenses being charged to customers or less than full cost recovery for scans that are not properly billed.	
Management Action Plan	
A.1	Management has implemented and will document a quality assurance process to ensure monthly billings are reviewed and confirmed via final schedule details to ensure all scans are accounted for.

A. Recharge Billings – Detailed Discussion

University policy (BFB-A-47, *University Direct Costing Procedures*), sets forth general procedures for direct costing in order to improve uniformity and consistency in the recording of direct costs throughout the University, and provides guidelines to ensure all elements of cost resulting from the use of services provided shall be recharged to users. We reviewed monthly billings from June 2018 and compared to scheduled activity on the three CTIPM MRI machines to determine whether activity was being consistently and accurately recharged to customers.

We noted that in June 2018 two scans at ROPCC were not billed. As part of the billing process, the ROPCC scheduler put together scan packets containing details of each scan performed on a monthly basis. The Administrative Director used these packets to generate the recharge billing details at the end of each month. We compared the packets for June 2018 to the monthly schedule and discovered two appointments on June 7th, 2018 and June 8th, 2018 were not billed. Per the Administrative Director, scan information for these two appointments were not included in the monthly packets, and therefore; they were not billed. Implementing a process to confirm all scans are billed will help ensure full cost recovery. The scheduler is in the process of sending the schedule information for these scans so they can be billed.

Additionally, our review disclosed the following scans were billed, but could not be traced to documented time on the scheduling calendars used to generate monthly billing details:

- Scan at ACTRI on June 23rd, 2018 at 10:00 am for \$1,024
- Scan at Keck on June 29th, 2018 at 10:00 am for \$1,792
- Scan at Keck on June 29th, 2018 at 1:00 pm for \$1,792
- Scan at Keck on June 30th, 2018 at 9:30 am for \$1,024
- Scan at Keck on June 30th, 2018 at 1:30 pm for \$1,024

The Administrative Director stated that the scheduler could have removed the appointments from the calendar after the monthly billings were processed due to cancellations. Establishing a process to confirm billed scans will help ensure customers are charged correctly. The Administrative Director is in process of setting up a monthly deadline for the study coordinators to review and make changes to the calendar.

B.	Recharge Rates
The recharge rate charged for data analysis was inconsistent with the approved recharge rate for CTIPM. In addition, it was not clear how the adopted rates were determined.	
Risk Statement/Effect	
Use of non-approved recharge rates is in violation of University Policy and can result in disparate charges to users that are not based on the cost of the service, and unallowable surplus balances for the recharge operation.	
Management Action Plan	
B.1	CTIPM will ensure that users are charged only at approved recharge rates and will document instances of any offsets. If any revisions to recharge rates are needed, these should be submitted to the Recharge Rate and Review Committee (RRRC) for formal campus approval, in compliance with University policy.

B. Recharge Rates – Detailed Discussion

University policy (BFB-A-47, *University Direct Costing Procedures*) states that “all elements of cost resulting from the goods or services provided shall be recharged to users based upon a previously authorized established price or standard pricing method uniformly applied to all users.”

We noted that the recharge rate used for data analysis was inconsistent with the RRRC-approved recharge rate. In April 2014, the Office of Vice Chancellor for Health Sciences received approval for recharges for CTIPM services. The approved proposal established the following hourly recharge rates:

- Analysis (\$250 for UC users and \$363 for non-UC users),
- Consultation (\$100 for UC users and \$145 for non-UC users), and
- Scans (\$640 for UC users and \$928 for non-UC users).

An additional request to add Contrast rates (\$100 for UC users and \$145 for non-UC users) and Clinical Read rates (\$200 for UC-users and \$289 for non-UC users for clinical read without contrast and \$250 for UC users and \$362 for non-UC users for clinical read with contrast) was approved by the RRRC in March 2016.

Two research studies that use the GE cosigned Keck MRI machine were recharged for Analysis services. Each study was charged different rates, neither of which were consistent with the approved Analysis recharge rate for UC-users of \$250 per usage. The rate per hour charged for all scans for UC-user project ABCD was \$640, and the rate charged per scan for UC-user project VETSA was \$730.86. CTIPM stated that the rate varies project to project, and differences included offsets for development time. 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.

C.	GE Cosigned Keck MRI Machine
There was no central oversight of the Keck machine to ensure the terms of the Master Agreement were being followed.	
Risk Statement/Effect	
Non-compliance with the terms of the agreement could put the University at risk of breach of contract.	
Management Action Plans	
C.1	CTIPM will provide enhanced oversight of the Keck machine to ensure all use is in accordance with an Individual Study Agreement, and will work with GE to ensure UCSD is aware of all studies approved for use.
C.2	Usage reports will be submitted timely, in accordance with the terms of the Master Agreement.

C. Keck Machine – Detailed Discussion

Machine Use

The Master Agreement, which governs the terms of use for the Keck MRI, requires that each study that desired to use the machine was required to submit a research study proposal and obtain an Individual Study Agreement with GE, and states that “any other use, such as, UCSD’s own clinical practice or research or third party research is prohibited and constitutes a material breach of” the agreement. Additionally, an Executive Advisory Board (EAB) comprised of the Associate Dean for Research, the Chair of Radiology, the Director of CTIPM, and the Chief Technology Officer of GE Healthcare and “appropriate General Managers for research and the respective modality for GE will oversee the Parties’ performance under the Research Program and will communicate about high-level needs and relationship progression.”

We were unable to verify all usage on the Keck MRI machine was associated with Individual Study Agreements. According to CTIPM’s Policies and Procedures for using the MRI machines, access is only granted to personnel who have received an MRI Safety Certification from CTIPM. When a clinical study has requested access to the Keck MRI machine, an Assistant Project Scientist in the Radiology Department confirms they have a valid Individual Study Agreement with GE and have received the proper training before they are allowed to access the calendar. During our review, we obtained 24 Individual Study Agreements from OCGA that have been granted use on the Keck MRI machine. We compared studies that have been granted access to schedule scans on the Keck calendar to the Individual Study Agreements; however, we were unable to fully reconcile the lists as the study titles on the Keck calendar were heavily abbreviated from the titles in the Individual Study Agreements, and the PI names did not always match. CTIPM indicated that in some cases GE granted UCSD investigators time on the machine without proper project review in accordance with the Master Agreement. The Director indicated that the EAB was not aware of this additional use.

Usage Reports

According to the Master Agreement, the Director is responsible for generating quarterly usage reports, which are to be prepared and delivered for “all GE Device Usage during such calendar quarter.” Quarterly usage reports for the Keck machine have not been submitted in accordance with the terms of the Master Agreement. The agreement was effective as of February 20, 2015. Per the Associate Director, only one usage report had been submitted to-date. A quarterly usage report for the period June 1, 2016 - May 31, 2017 was submitted to GE. A report for the period June 1, 2017 - May 31, 2018 has been prepared for approval by the Director.

Implementing centralized oversight of the Keck machine will help to ensure the terms of the Master Agreement are met.