February 9, 2024

GARY S. FIRESTEIN, MD
Director, Altman Clinical and Translational Research Institute
Senior Associate Vice Chancellor for Health Sciences
0990

Subject: ***Altman Clinical and Translational Research Institute***
Report 2024-16

The final report for Altman Clinical and Translational Research Institute Report 2024-16, 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.

Christa Perkins
Digitally signed by Christa Perkins
Date: 2024.02.09 08:09:32 -08'00'

Christa Perkins
Director
Audit & Management Advisory Services

Attachment

cc: Judy Bruner
Alexander Bustamante
Bernadette Cale
John Carethers
Su-Yin Chang
Rina Davison
Michael Hogarth
Eric Mah
Pierre Ouillet
Carlos Rojas
Ron Skillens
David Smith

UC San Diego

AUDIT & MANAGEMENT ADVISORY SERVICES

Altman Clinical and Translational Research Institute
Report No. 2024-16
February 2024

FINAL REPORT

Performed By:

Laurie Ward, Senior Auditor
John Teevan, Manager

Approved By:

Christa Perkins, Director

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I. EXECUTIVE SUMMARY

Audit & Management Advisory Services (AMAS) has completed a review of the Altman Clinical Translational Research Institute (ACTRI) as part of the approved audit plan for Fiscal Year 2023-24. The objective of our review was to evaluate whether ACTRI internal controls provided reasonable assurance that business processes and financial oversight are effective, conducted in compliance with applicable University policy, and result in accurate financial reporting.

Based on our review, we concluded that ACTRI internal controls provided reasonable assurance that business processes and financial oversight are effective, conducted in compliance with applicable University policy, and result in accurate financial reporting.

We observed that ACTRI leadership continues to evaluate strategies to maximize capacity and improve utilization of space and resources given anticipated future growth. These evaluations include analyzing daily visit frequency, completed visits by day, and average daily visits with projections for future capacity that is expected to be reached in the next two to three years. Management has determined a maximum number of visits per day that can be accommodated (47) based on current space and staffing; however, there are limitations around fasting, sample shipping times, and desirable time slots and/or days of the week.

We reviewed management's analyses and forecasts, verified the accuracy of the data to support these estimates, and concluded that the forecasts appear reasonable. While certain initiatives are already underway, there appears to be further opportunities for optimizing capacity and the utilization of space and resources. These factors are included in management's ongoing discussions about additional measures to be implemented in the near future. In order to avoid turning down studies or grants in the future, innovative space and resource utilization has been needed. ACTRI is currently evaluating methods and making adjustments to maximize space and utilization including the following:

1. Building out additional space for eight rooms in the ACTRI building basement which has already been approved and is currently in process;
2. Changing nurse shift schedules effective November 27, 2023 from four ten-hour shifts to five eight-hour shifts to ensure sufficient coverage at peak times and reduce underutilized nursing staff time in the down times typically in the afternoons;
3. Analyzing ways to identify and prioritize morning requests for appointments; and
4. Regular brainstorming with the Faculty Advisory Committee to discuss ideas and recommendations for future incentives and/or ways to maximize current space and resources.

We noted that there were two projects with deficits over $25k; however, ACTRI was actively working on resolving each. ACTRI deficits are included in the recently implemented quarterly deficit review policy and procedures managed by the VCHS Controller's Office, therefore deficit resolution will be addressed as part of that process. Also, we observed that the process for managing the Pyxis device, medications and controlled substances was in compliance with UC policy and procedures. ACTRI partners with UCSDH Pharmacy and IDS to manage study medications, including controlled substances.

We did identify opportunities for improvement in recharge procedures that could be enhanced to ensure accurate and more consistent billing. These opportunities for improvement are discussed further in the balance of the report.

A. Recharge Billing and Management
The recharge rate charged for clinic and coordinator services was inconsistent with the approved recharge rate for ACTRI. Three out of thirty recharge transactions reviewed had inaccurate recharge rates invoiced, and new rates, approved effective September 1, 2023, were not implemented in a timely manner.

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 Altman Clinical Translational Research Institute (ACTRI) as part of the approved audit plan for Fiscal Year 2023-24. This report summarizes the results of our review.

The ACTRI mission is to facilitate the research of others by providing resources, training, and collaboration opportunities for ACTRI scientists, health care providers, and the community. The ultimate goal of ACTRI is to create a working space where medical treatment and clinical research are co-located in close geographic proximity while providing state of the art translational research laboratories and research participant space. The ACTRI receives substantial funding from a Clinical and Translational Science Award (CTSA) to accelerate laboratory discoveries into treatments for patients. The CTSA support allows ACTRI to innovate across a broad range of Clinical translational science areas and integrate their diverse research communities into their efforts. ACTRI provides funding, training, staffing, consultation, space and equipment to investigators at UC San Diego (UCSD) and partner institutions. In addition to the CTSA award, ACTRI receives budgetary support from the Vice Chancellor of Health Sciences (VCHS).

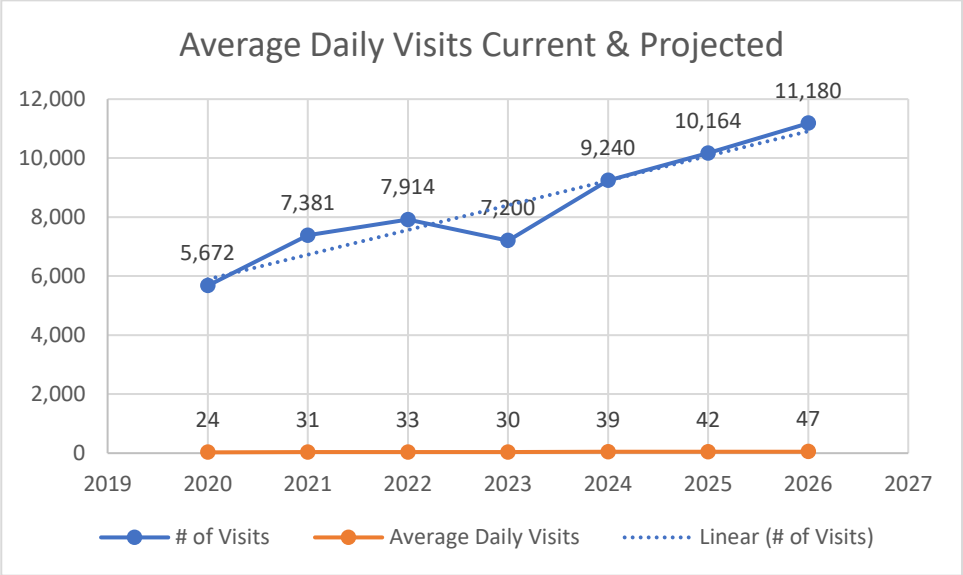
The ACTRI includes six divisions:

- *Center for Clinical Research (CCR)*: includes the services that facilitate performing all aspects of clinical research including the ACTRI Clinic, Research Coordinator & Language Translation Services, Regulatory Support, Project Management Services, IDS Pharmacy, MRI/Imaging, Research Ethics and Data Safety Monitoring;
- *Biomedical Informatics (BMI)*: supports software for managing clinical trials and observational studies, in addition to tools to query clinical records;
- *Translational Research Technology (TRT)*: provides lab services for ACTRI members and external collaborators;
- *Community Engagement*: includes Community Research Participants, Center for Community Health, Dissemination & Implementation Science Center and Population Research Scientific Methods;
- *Education, Training and Career Development*: provides funding, training, seminars and mentorship to researchers and students who want to advance health sciences; and,
- *Translational Research Alliance:* in order to make research discoveries more effective and useful to all, ACTRI provides scientists and community leaders with resources and information and encourages interactions between all the different people.

The ACTRI occupies approximately 25,000 square feet at 9452 Medical Center Drive in La Jolla, of which 8,000 square feet is devoted to clinical research. ACTRI has in excess of 40 clinical rooms including those designated for infusion, overnight stays, treatments, procedures, exercise, ultrasounds, fiber scans, dual x-ray absorptiometry (DEXA) scan[1], phlebotomy and consults. Suites are equipped with networked computers and printers.

[1] DEXA (dual x-ray absorptiometry) scans measure bone density (thickness and strength of bones) by passing a high and low energy x-ray beam (a form of ionizing radiation) through the body, usually in the hip and the spine.

In addition to this existing space, ACTRI is currently adding an additional eight rooms in the building's basement. ACTRI currently supports over 150 active studies. As demonstrated in the graph below, the current average for FY 2023 is 30 visits daily, with slowed growth during the pandemic which is recovering. Current clinic space without any changes is predicted to be at maximum capacity by 2026, with 11,180 annual visits equivalent to 47 average daily visits, using a conservative estimate of 10% growth every year. This report is assuming 240 clinic days in a year or 20 days a month.



Recharge Activities

ACTRI services that have individual established recharge rates include costs for the following:

1. ACTRI Clinic: the rooms for exams, consultations and overnight studies, a kitchen and specialized equipment;
2. Clinical Research Coordinator (Coordinator) Services: assistance with conducting a study whether it is overseeing screening and enrollment, conducting the informed consent process, conducting study visits and many other tasks that can be delegated to run the study;
3. BMI: software for managing clinical trials and observational studies and tools to query clinical records;
4. Biostatistics, Epidemiology and Research Design (BERD): statistical support at all research phases;
5. TRT Laboratory: lab services;
6. Regulatory Support: Clinical Trial Support Services staff with regulatory experience can assist researchers with various IRB and ancillary committee submissions;
7. Project Management: services to ensure that trials are set up, enrolled, conducted, and reported on-time and according to budget;
8. Dissemination and Implementation Science Center (DISC) Services: training, consultation, technical assistance and mentoring to advance dissemination and implementation with a local, national and global impact;
9. Center for Computational Biology and Bioinformatics (CCBB): bioinformatics expertise services for data analysis, biological interpretation grant writing and training; and,

10. Evaluation Services: evaluation services for the design of grant proposals, ongoing projects, publication and dissemination to support ACTRI's program and leadership efforts to develop goals, targets and relevant metrics of success.

ACTRI Coordinator services are provided on an hourly basis or can be assigned at a percent effort to an individual investigator for a specified period of time, and may be tailored to support a single service or multiple services. ACTRI provides services and fees based on what is needed by the Principal Investigator(s) (PI), which could vary from the beginning to the end of a study. ACTRI Coordinators work on studies that range from drug therapy for liver cancer to metabolic studies, with duties that encompass scheduling subject visits and managing information databases to measuring vital signs, drawing blood samples, and performing EKGs and lab work. ACTRI does not process recharges for pharmacy or the MRI research center.

ACTRI utilizes a system called Clinical Conductor, a clinical trial management system, to build all the research studies, schedule clinic visits and apply charges. In addition to Clinical Conductor, ACTRI uses Harvest, a time tracking software for tracking clinician/coordinator time on each of the research studies. Reports are downloaded from Clinical Conductor and Harvest at the end of each month, prepared to meet the technical requirements for Oracle[2], and then uploaded to the ACTRI recharge application in order to transmit recharges to Oracle. Oracle uploads the charges and applies the charges to the respective study chart strings in Oracle which creates a monthly billing recharge invoice for each study.

Controlled Substances

ACTRI follows UCSD Health (UCSDH) requirements for medications including controlled substances. The Investigational Drug Service (IDS), a division of the UCSDH Pharmacy Department, manages investigational medications, which include a limited number of controlled substances, for the clinical studies at ACTRI. The Clinic Manager manages clinical standard of care drugs and a small amount of controlled substances used during studies, which are stored in the ACTRI Pyxis[3] machine.

Financial Results

According to the UCSD Financial Reports[4] for Fiscal Year (FY) 2022-2023, ACTRI had approximately $34.3 million in total revenue including contracts and grants of $13.8 million (40%), $40.6 million in total expenses and a net loss of $6.3 million[5]. ACTRI has an ending net position of $8.2 million before deducting capital assets. Payroll and compensation were approximately 37% of total expenses. Recharge revenue for external and internal activities and Vice Chancellor (VC) Dean Allocation support accounted for $3.2 million and $2.95 million (each 9% of total revenue), respectively. The ACTRI business model for cost recovery is focused on high utilization for the benefit of the overall enterprise. For example, recharge rates do not include a facilities fee normally charged by the Health System for clinical services in order to allow investigators to stay within their budgets. As a result, the Center anticipates a structural operating deficit which is offset from other sources like indirect cost fund flow from clinical trials.

[2] UC San Diego utilizes Oracle Financial Cloud (OFC) as the financial system for the University.
[3] Pyxis is an automated medication dispensing system supporting decentralized medication management.
[4] OFC FIS Net Operating Results and Fund Balance Report.
[5] Management has indicated that this deficit is related to at least two mitigating factors: (1) the timing of revenue posting from the NIH NCATS U award (PI: Dr. Gary S. Firestein) as a substantial source of funds for ACTRI which does not align with UCSD's fiscal year, and (2) the recent reconfiguration of the SAVC organization unit in the VCHS office that led to a one-time change in operating unit and cost centers and is recorded as an expense. The deficit is not expected at this same level next fiscal year.

III. AUDIT OBJECTIVE, SCOPE, AND PROCEDURES

The objective of our review was to evaluate whether ACTRI internal controls provided reasonable assurance that business processes and financial oversight are effective, conducted in compliance with applicable University policy, and result in accurate financial reporting. In order to achieve our objective, we performed the following:

- Reviewed the following:
  - Applicable University and federal policies and guidance including UC BFB-A47 and UC BFB-56;
  - The ACTRI website, prior audits, capacity study evaluations and conducted a walk-through of the ACTRI clinic location;
  - Data support for ACTRI clinic utilization analyses, including verification of the data;
  - The standard operating procedures (SOPs) for ACTRI controlled substances;
  - OFC Net Operating Results and Fund Balance Reports for FY2022-2023;
- Interviewed the following key administrative personnel to understand how space and capacity are evaluated for present and future growth, and gain an understanding of the ACTRI services including the clinic trial process and recharge management:
  - Associate Dean, Chief Administrative Officer;
  - Clinic Manager;
  - Operations & Research Services Director;
  - Director of Finance and members of the Finance team;
  - Clinical Operations Specialist;
  - Clinical Research Program Manager; and
- Interviewed the IDS Senior Pharmacy Manager to gain an understanding of IDS management of controlled substances at ACTRI and internal management including the one ACTRI Pyxis machine.
- Consulted with the Executive Director of Costing Policy & Analysis (CPA) and reviewed approved rates and supporting documents provided by the CPA office;
- Obtained and evaluated the most recent recharge proposal and methodologies for the ACTRI recharge services including ACTRI Clinic and Coordinator Services;
- Reviewed and examined the following:
  - Reports obtained from the Finance team for March 2023 through August 2023 prior to submitting to the recharge application;
  - The Financial Activity Reports (FARs) provided by the Clinical Operations Specialist from Clinical Conductor for visits between June 2023 and August 2023; and
  - The SOP for recharge reconciliations and conducted a walk-through of the process from Harvest, Clinical Conductor, and the recharge application through to billing.
- Evaluated:
  - A judgmental sample of 20 visits consisting of Clinic and Coordinator recharge transactions selected from the Finance Team spreadsheets. Traced and verified to supporting documentation from Harvest, Clinical Conductor, and Oracle Expanded Project Budget Reports and evaluated for completeness and validation of the appropriate and authorized recharge amounts; and,

- A sample of 10 September 2023 visit charges from the Expanded Project Summary report to verify the appropriate new rate was applied. Traced the charge back to the Clinical Conductor system and reports.

Our review focused on clinical trial utilization, oversight, recharge operations and related clinic operations. A prior report, AMAS Project #2018-22, focused on CTSA award management.

IV. CONCLUSION

Based on our review, we concluded that ACTRI internal controls provided reasonable assurance that business processes and financial oversight are effective, conducted in compliance with applicable University policy, and result in accurate financial reporting.

We observed that ACTRI leadership continues to evaluate strategies to maximize capacity and improve utilization of space and resources given anticipated future growth. These evaluations include analyzing daily visit frequency, completed visits by day, and average daily visits with projections for future capacity that is expected to be reached in the next two to three years. Management has determined a maximum number of visits per day that can be accommodated (47) based on current space and staffing; however, there are limitations around fasting, sample shipping times, and desirable time slots and/or days of the week.

We reviewed management's analyses and forecasts, verified the accuracy of the data to support these estimates, and concluded that the forecasts appear reasonable. While certain initiatives are already underway, there appears to be further opportunities for optimizing capacity and the utilization of space and resources. These factors are included in management's ongoing discussions about additional measures to be implemented in the near future. In order to avoid turning down studies or grants in the future, innovative space and resource utilization has been needed. ACTRI is currently evaluating methods to maximize space and utilization, while at the same time minimizing financial loss, including the following:

1. Building out additional space for eight rooms in the ACTRI building basement which has already been approved and is currently in process;
2. Changing nurse shift schedules effective November 27, 2023 from four ten-hour shifts to five eight-hour shifts to ensure sufficient coverage at peak times and reduce underutilized nursing staff time in the down times typically in the afternoons;
3. Analyzing ways to identify and prioritize morning requests for appointments; and
4. Regular brainstorming with the Faculty Advisory Committee to discuss ideas and recommendations for future incentives and/or ways to maximize current space and resources.

We noted that there were two projects with deficits over $25k; however, ACTRI was actively working on resolving each. ACTRI deficits are included in the recently implemented quarterly deficit review policy and procedures managed by the VCHS Controller's Office, therefore deficit resolution will be addressed as part of that process. Also, we observed that the process for managing the Pyxis device, medications and controlled substances was in compliance with UC policy and procedures. ACTRI partners with UCSDH Pharmacy and IDS to manage study medications, including controlled substances.

Harvest and Clinical Conductor were effective in tracking time incurred related to clinical studies, enabling accurate effort reporting for recharge activities for individual studies. However, we did identify opportunities for improvement in recharge procedures that could be enhanced to ensure accurate and more consistent billing. These opportunities for improvement are discussed further in the balance of the report.

V. OBSERVATIONS REQUIRING MANAGEMENT ACTION

A.	Recharge Billing and Management
The recharge rate charged for clinic and coordinator services was inconsistent with the approved recharge rate for ACTRI. Three out of thirty recharge transactions reviewed had inaccurate recharge rates invoiced, and new rates, approved effective September 1, 2023, were not implemented in a timely manner.	
Risk Statement/Effect	
Inaccurate or delayed implementation of new recharge rates charged can lead to incorrect expenses being charged to clients or less than full cost recovery for services that are not properly billed.	
Management Action Plans	
A.1	ACTRI management reviewed the three errors discovered and determined that charges would not be billed retroactively; however, rates would be corrected for future billings.
A.2	New rates effective September 1, 2023 for clinic and coordinator services have been implemented for September transactions as of November 30, 2023, and October and November recharges will be processed with the new rates in the immediate future.
A.3	ACTRI management will ensure that users are only charged at approved rates, any instances of offsets will be documented and any errors corrected as deemed necessary.

A. Recharge Billing and Management – 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 reviewed monthly billing transactions from June 2023 through October 2023 and compared to approved rate schedules to determine whether activity was being consistently and accurately recharged to clients.

We noted that three out of 30 (10%) recharge transactions reviewed were not billed accurately resulting. The Operations Specialist reviewed these charges and it was determined that additional charges would not be billed at this time; however, the correct charge moving forward would be implemented. A summary of these recharge transactions with variances is presented in the table below:

Date of Service	Service	Issue	Amount Charged	Correct Charge Amount	(Lost Revenue) or Overcharged
7/18/23	Treatment/ Overnight Room	Error in room rate applied to charge.	$440	$428	$12
6/5/23	Registered Nurse Rate Per Hour	Old rate per hour of $102 instead of $121.	$398	$440	($42)
6/1/23	Study Visit	Missing a $24 phlebotomy charge.	$119	$143	($24)
		TOTAL	**$957**	**$1,011**	**($54)**

The primary system used to schedule and create charges, Clinical Conductor, has several points of manual input. Rate increases cannot be implemented automatically and instead must be entered manually line by line or with a spreadsheet uniquely coded to update a batch of charges. For any studies opened prior to September 1, 2023, the Operations Support Specialist is required to apply a formula to the applicable spreadsheet to account for the rate increase effective September 1, 2023. A rate increase of either 10% for grant-funded studies or 20% for commercially funded studies is automatically applied. Any new studies implemented will have the new rate manually entered at the initial build out of the study and will not need to be corrected going forward. The list of studies in the spreadsheet will just be reduced going forward as the studies before the new rate took effect are closed and drop off.

Typically, per the ACTRI Recharge Rate Reconciliation SOP, following the close of the previous month and by the 15th of the following month, the Operations Support Specialist accesses Clinical Conductor and downloads the FAR, a report of the appointments, and recharges from the first to the last day of the previous month. The Operations Support Specialist then completes the following steps: 1) confirms the visits occurred and completes any visits that are open; 2) reviews the final numbers and confirms the recharges via a spot audit; and 3) emails the reconciled FAR to the ACTRI Fund Manager. Separately, the ACTRI Fund Manager downloads the previous month's FAR and applies the rate increase formula and confirms that the numbers agree to the FAR received from the Operations Support Specialist.

New rates effective September 1, 2023 were processed for September activity at the end of November 2023. When the Finance team verified the amounts after all corrections had been made, there was a noted difference of $960, equivalent to an error rate of less than 1%[6]. Management is confident with the process using the new rates, and will continue with October and November 2023 and subsequent recharges. The Fund Manager works with the Operations Support Specialist to reconcile and make any appropriate adjustments to Clinical Conductor if there are any noted differences. Once the FAR is finalized, it is submitted to the recharge application which applies the charges to the respective study chart strings in OFC.

October and November 2023 and other future recharge billings for studies started before the new rate's effective date of September 1, 2023 will utilize the formula for the new rate. If there is an additional update to recharge rates in the future a new spreadsheet with a new formula will be created to apply to current studies at that time.

[6] Based on September recharges of $116,873.