UNIVERSITY OF CALIFORNIA, DAVIS
INTERNAL AUDIT SERVICES

University of California, Davis Health System
Contract Management
Project #11-11

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Fieldwork Performed by:

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Reviewed and Approved by:

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I. BACKGROUND

The Health System Contracts (HSC) office is responsible for the health care and business contracting needs of the UC Davis Health System (UCDHS). The types of agreements processed include, but are not limited to, the following:

- Managed care contracts;
- Faculty service agreements, unrelated to research;
- Healthcare payer contracts (including private, Federal, State and Local Government);
- Independent consultant agreements, unrelated to research;
- Independent contractor agreements for professional services, unrelated to research;
- Affiliation agreements;
- Training agreements;
- Facility transfer agreements;
- Intergovernmental Personnel Act (IPA) agreements (non-UCDHS awarded research funding);
- Expert witness agreements when primary to course and scope of faculty appointment;
- Rights and reimbursement of expenses affiliated with contracts and service agreements;
- Facility use agreements and permits of less than one year in duration; and
- Clinical trial research agreements.

HSC negotiates and executes agreements for industry funded clinical trials defined as the controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol. HSC assumed responsibility for executing clinical trial agreements (CTAs) from the Office of Research effective April 1, 2009.

HSC reports workload statistics and the status of CTAs in process monthly to the Translational Research Integration and Compliance Committee (TRICC) charged with streamlining and improving processes and procedures related to clinical and translational research operations. HSC also provides data on newly executed CTAs and modifications to existing CTAs to the UC Office of the President (UCOP) on a quarterly basis.

II. AUDIT PURPOSE AND SCOPE

As part of the planned reviews for fiscal year 2010-2011, Internal Audit Services conducted a review of UC Davis Health System Contracts (HSC) office. The purpose our review was to assess the effectiveness and efficiency of the current process and procedures related to contracting for privately sponsored clinical trials.

To complete our review, we identified University contracting policies and procedures and examined HSC practices related to the execution of clinical trial agreements with private industry sponsors. We also interviewed HSC staff and UC Davis School of Medicine (SOM) personnel involved in the clinical trial process. In addition, we analyzed clinical trial implementation data and HSC workload statistics, and we evaluated selected clinical trial agreements for compliance with University policies and procedures. Fieldwork was conducted between July 2010 and September 2010, and covered clinical trial agreements negotiated during the period April 2009 through June 2010.

III. CONCLUSION

We concluded that HSC has developed and implemented an efficient and effective process for negotiating clinical trial agreements (CTAs) with private industry sponsors in accordance with University policies and procedures. We determined that CTAs were appropriately reviewed for compliance with University policy and state law under University guidelines for research involving human subjects and clinical trials, and that any problematic provisions outside of policy were raised to the appropriate level for resolution. We also determined that required approvals from the Institutional Review Board (IRB) and Conflict of Interest Committee were obtained along with principal investigator approval of the agreement and related budget before the CTAs were executed by the HSC director. Moreover, SOM personnel involved in the clinical trial process reported that HSC is proactive in following up and providing feedback on issues encountered during the negotiation process and responsive to inquiries regarding status and requests for assistance.

SOM personnel also reported that turnaround time for clinical trial proposals has improved substantially with the transfer of responsibility to HSC. We confirmed that HSC had executed 121 CTAs since assuming responsibility in April 2009, for an average of approximately 8 CTAs per month versus 7 CTAs per month during the previous 24-month period. Newly negotiated agreements accounted for 68% of the CTAs; whereas 32% of the CTAs were developed in accordance with a master agreement. The average length of time to process a new CTA was 40 days with a median time of 24 days. The average length of time to process a CTA based on a master agreement was 21 days with a median time of 13 days.

HSC also processed 107 amendments to existing CTAs in an average time of 27 days with a median time of 12 days.

Although HSC has established an effective methodology for monitoring and reporting on the status of CTAs for management purposes, we identified additional data elements related to clinical trial implementation, such as the timeliness of IRB and department chair approval, that should be monitored to identify trends requiring remedial action to mitigate factors that impede the efficiency and effectiveness of the CTA process. Since this issue is beyond the control of HSC, it has been referred to the SOM Office of Research and no other recommendations to HSC are warranted based on our review.

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