UT SOUTHWESTERN
MEDICAL CENTER

Office of Internal Audit

December 5, 2012

Kenneth Shine, M.D.
Executive Vice Chancellor for Health Affairs
The University of Texas System
601 Colorado Street
Austin, TX 78701

Dear Dr. Shine:

Enclosed for your information is a copy of the University of Texas Southwestern Medical Center Internal Audit Report - 12:16 Research Compliance.

I concur with the auditors' recommendations. Four recommendations are in process.

Sincerely,

Daniel K. Podolsky, M.D.

Enclosure

cc: Arnim E. Dontes
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The University of Texas Southwestern Medical Center

Internal Audit Report 12:16
Research Compliance

December 5, 2012

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University of Texas Southwestern Medical Center
Internal Audit Report 12:16
Research Compliance
FY 2012

AUDIT REPORT
DECEMBER 5, 2012

Daniel K. Podolsky, M.D., President
The University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard, MC 9002
Dallas, Texas 75390-9002

Dear Dr. Podolsky:

The University of Texas Southwestern Medical Center (Medical Center) Office of Internal Audit has completed its 12:16 Research Compliance audit as detailed below.

Executive Summary

The objective of this audit was to determine whether elements of a research compliance program are in place to adequately monitor and manage the Medical Center's research high risk areas. Examples of research activity include basic research, pre-clinical research, clinical trials research and the supporting grants and contracts. The Medical Center receives over $417 million in funding annually for about 3,500 research projects. This was a UT System required audit from the 2012 Medical Center audit plan and covered the period of September 1, 2010 through October 31, 2012. To evaluate effectiveness, this audit focused on the sufficiency of the institutional risk assessment for research compliance at the Medical Center, including training, monitoring and reporting associated with the mitigation of those risks. To achieve our audit objectives we determined responsible parties, conducted interviews, performed walkthroughs, reviewed policies and documentation on file, and analyzed procedures and reviewed processes.

The Research Administration Office has developed the elements of a research compliance program that adequately monitor and manage the Medical Center's research high risk areas, with the exception of clinical trials which is in process. In order to enhance controls in the management of risks associated with clinical trials billing compliance the following recommendations were made. 1) Clinical Trials Financials Support Function - The organizational structure and staffing levels of the Clinical Trials Financials support function of Research Administration should be finalized. This would ensure adequate services are provided to investigators and research personnel in the conduct of clinical research in compliance with applicable rules and regulations. 2) Clinical Trials Compliance Training - Research Administration, Billing Compliance and the Office of Compliance should continue to collaborate to determine necessary clinical trials billing compliance training requirements, to obtain policy approvals and training budgets, and identify and enroll department personnel required to complete compliance

training. 3) Clinical Trials Billing Compliance Monitoring - Formal approval of the Research Billing Compliance Plan, monitoring activities and reinstatement of Billing Compliance Monitoring positions in the next budget cycle would ensure allocation of dedicated resources to clinical trials billing compliance. 4) Clinical Trials and Research Policies - Finally, Research Administration should coordinate with the responsible offices in updating the Clinical Trials and Research Policies outlined in the Handbook of Institutional Policies and Operating Procedures to ensure accomplishment of stated goals and missions.

Background

The Medical Center receives ongoing support from federal agencies such as the National Institutes of Health, along with foundations, individuals and corporations that provide more than $417 million per year to fund about 3,500 research projects. It is because of this large amount of funding that research compliance is considered an institutional high risk. Faculty and staff members who direct sponsored research projects under the Medical Center have an important public, as well as personal responsibility to manage those projects diligently and ethically. The Medical Center has made it the responsibility of every research investigator to maintain the integrity of his/her projects by keeping accurate, permanent and auditable records of all experimental protocols, data and findings.

Responsibility for research compliance spans widely throughout the Medical Center. Examples of research activity include basic research, pre-clinical research, clinical trials research and the supporting grants and contracts. Various compliance requirements are associated with research activity and have necessitated collaborative efforts from different Medical Center departments and offices to ensure overall adherence. While the Medical Center President is ultimately responsible for institutional research compliance, the task of managing this collaborative effort has been delegated to the Vice President of Research Administration (VPRA). Research Administration is responsible for the development of research compliance risk assessments, training procedures, monitoring procedures and reporting procedures. Research Administration is tasked with providing compliance oversight for all research projects. There are a number of regulatory bodies that must be complied with when conducting research. To address these issues the Research Administration Office offers pre-award and post-award administrative services.

An effective compliance program provides several advantages and benefits to the adopting entity. It addresses the Government's and research community's mutual goals of ensuring good stewardship of Federal funds by eliminating erroneous or improper expenditure of Federal research funds, improving administration of grants from both the Federal Government and private sources, and demonstrating to employees and the community at large the institution's commitment to honest and responsible conduct. An effective research compliance program facilitates the accomplishment of (1) Identification and correction of potential unlawful and unethical behavior at an early stage; (2) Encouraging employees to report potential problems and allowing for appropriate internal inquiry and corrective action; (3) Minimizing any financial loss to the

institution and the Government; and (4) Reducing the potential negative findings during government audits and investigations.

Audit Objectives
The objective of this audit was to determine whether elements of a research compliance program are in place to adequately monitor and manage the Medical Center's research high risk areas. Establishment, at both the institutional level and within specific research areas, of the following key elements was evaluated to determine the adequacy of program elements:

- Overall institutional responsibility for research compliance assigned to a member of executive management.
- Responsible parties assigned for each specific high risk research area.
- Performance of an institutional risk assessment for research compliance that is of sufficient detail to identify high research risk areas, as well as specific risks within each of those areas.
- Plans or processes that effectively monitor research risks, that address research compliance training needs, and that keep appropriate members of operational and executive management apprised regarding the compliance status of research compliance high risks.

Scope and Methodology
The audit covered the period of September 1, 2010 through October 31, 2012. Our examination was conducted according to guidelines set forth by The University of Texas System Administration Policy UTS129 "Internal Audit Activities", the Regents' Rules and Regulations, and the *Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.* To achieve our audit objectives we determined responsible parties, conducted interviews, performed walkthroughs, reviewed policies and documentation on file, analyzed procedures and reviewed processes.

AUDIT RESULTS/RECOMMENDATIONS
Audit recommendations are detailed below.

1. **Clinical Trials Financials Support Function**
   The VPRA is coordinating with Academic Administration and the Compliance Officer to introduce necessary clinical research support processes. The Clinical Trials Financials (CTF) group is a Research Administration support function, currently being established, consisting of three full-time Clinical Research Finance Analyst positions. The CTF group is working within the Office of Compliance, on a temporary basis receiving direction from the Compliance Officer. Further enhancements to the CTF group such as staffing requirements, including the addition of a Director level position, new analyst/specialist positions and repurposed Grants and Contracts positions, are in process.

Major goals of a CTF support function generally include providing services to the investigators and research personnel in the conduct of clinical research in compliance with the required federal, state, and local regulations. They often include providing support and consultation on regulations and standards of practice governing human subject research, providing education and training, developing standards and processes, conducting quality improvement efforts and creating a collaborative environment among the research teams.

Recommendation

Processes, staffing and final organization for the CTF group should be in place to support the research department users in the utilization of the new clinical trials management system (Velos) as it is integrated with the medical practice and billing management portions of the Epic system. A target date should be established to ensure controls are functioning as designed.

Management Response

The VPRA has proposed the initial staffing and organizational structure to senior leadership at UT Southwestern and it has been approved. The Office of Clinical Research Facilitation will be established September 1, 2012 for the next fiscal period. Research Administration is in the process of transferring the staff, recruiting the new positions and establishing the "organization" within the financial and human resource system. Following the recruitment of key positions, policies, processes and the implementation of the goals outlined in the approved proposal will be established. A formal implementation plan will outline the key elements and the target will be to complete within year one of the creation of the office.

Implementation Status: In Process
Implementation Date: August 31, 2013

Responsible Personnel:
Vice President, Research Administration

2. Clinical Trials Compliance Training

New clinical trials billing compliance training elements were introduced in the past several months and additional focus and approved resources are needed to complete the training implementation. Research Administration, Billing Compliance and the Office of Compliance administered recent training as follows.

a. Billing Compliance introduced a Research Billing Compliance training module in November 2011. This on-line training requires approximately one hour and is designed to assist research department personnel, financial professionals and billing staff in understanding their roles and responsibilities in research billing compliance. Fourteen of twenty-one department personnel enrolled for training in 2011 completed the module. This training is required annually beginning with May 2012. Clinical Departments and Hospital Divisions are responsible for

providing Billing Compliance with names of employees who require training; however, these are not yet completed. The Medical Center's MSRDP Billing Compliance Plan mandates a minimum of two billing compliance training hours per year for healthcare providers, but it does not specifically address clinical trials or the clinical trials coverage analysis (CTCA) process.

b. Three two-day classroom training sessions covering CTCA were introduced during January-March 2011. The training sessions were intended to provide participants with information on the coverage analysis process and benefits of the new Velos clinical trials management system. Approximately 150 research department, billing compliance and academic information systems (AIS) personnel completed these CTCA training sessions. No additional classes were since provided. CTCA training is currently not required, but it is to be required of all department faculty and/or staff members who will perform a coverage analysis as outlined in a proposed Clinical Trials Billing Compliance Research Policy 153 (RES-153). The number of research personnel who will need to perform coverage analysis or access to the system functionality, or the number of required training sessions has not been determined. There is possible funding for campus-wide CTCA training in the operating budget of Research Administration in the form of allocated maintenance and operations (M&O). Management efforts have focused on achieving the Velos clinical trial management system implementation and obtain policy approval.

Clinical trials billing compliance pertains to the identification of clinical research items or services that can or cannot be billed to third-party payers, assurance that processes are in place to bill payers only for items or services that research billing rules allow to be billed, and harmonization of relevant areas of study documents in accordance with research billing rules. The planned expectation of the Medical Center will require department faculty and/or staff members who will perform a coverage analysis to complete training sponsored by or approved by Research Administration and the Office of Compliance.

Recommendations (a & b)

Research Administration, Billing Compliance and the Office of Compliance should collaborate to determine necessary clinical trials billing compliance training requirements. These should be formally communicated to department personnel required to attend training and reference specific available training resources including on-line sessions and other training modules in order to meet the stated requirements. A training curriculum or matrix based on specific needs of participants should be considered. CTCA training may be structured to include classroom as well as on-line sessions in order to make the training process more accessible and efficient.

Management approval of Policy RES-153 should ensure adequate communication and administration of required coverage analysis training. The number of department personnel who will need to perform coverage analysis

and estimated number of required training sessions should be established. A CTCA training budget should be developed. Verification of required and completed training should be performed to ensure clinical research billing and policy compliance.

Management Response
The Office of Clinical Research Facilitation (formerly the CTF group) will work with the Office of Compliance to assess clinical department and the School of Health Professions interest in participating in coverage analysis training. This assessment will be completed by December 7, 2012. If there is sufficient interest expressed by clinical departments or by the School of Health Professions, a formal coverage analysis training program will be developed and implemented no later than January 31, 2013.

In addition, the Office of Clinical Research Facilitation will work with Billing Compliance to expand the offering of web-based training (through the eHealthcareIT and My Learning programs) on clinical research billing compliance to all clinical providers and clinical department/School of Health Professions billing and charge capture staff. Affected clinical providers will be identified through the use of the MDaudit Professional (billing compliance auditing) software. Affected clinical department/School of Health Professions billing and charge capture staff will be identified through the Billing Compliance Office. The expected implementation date for this training is February 1, 2013.

Implementation Status: In Process
Implementation Date: February 1, 2013

Responsible Personnel:
Vice President, Research Administration

3. **Clinical Trials Billing Compliance Monitoring**
Clinical trials billing compliance monitoring has not been made fully functional. Billing Compliance, in collaboration with Research Administration and the Office of Compliance are responsible for developing and administering a clinical trials billing compliance plan, which includes monitoring/quality review activities.

   a. Currently, University Hospitals Billing Compliance staff, reporting to the University Hospitals Director of Compliance, performs Hospital billing compliance monitoring. Billing Compliance staff, reporting to the Director of Billing Compliance, performs Physician and Professional billing compliance monitoring. Both functions report to the Compliance Officer in the Office of Compliance. There is no comprehensive compliance monitoring of clinical trials billing activities that spans the coverage analysis of a research study, applicable professional billing, hospital in-patient and out-patient billing. Clinical trials billing services are reviewed only if they appear in the random sample generated for

Professional and Hospital Billing Compliance quarterly reviews. Some clinical trials billing items were identified and reviewed as part of the First Quarter 2012 Hospital billing. They are currently used for educational purposes only to ensure correct billing. No official grading score is assigned to the clinical trials research provider or billing staff.

b. The plan for clinical trials billing compliance, including monitoring activities, and dedicated staffing for clinical trials billing compliance monitoring are not yet finalized. A draft of this plan is under development by Billing Compliance with target presentation to the University and Professional Billing Compliance Committee (UPBCC) in the second half of calendar year 2012. Additionally, there is a plan by the Office of Compliance to request the funding for three billing compliance monitoring positions for fiscal year 2013. Those positions had been eliminated in previous budget cycles. The additional resources would be dedicated to clinical trials billing compliance.

Adequate clinical trials billing compliance monitoring ensures effective application of policies, procedures and regulatory requirements related to clinical research billing. This includes an effective audit/monitoring plan, dedicated staffing and execution of the plan that involves on-going review of clinical study billing activities. A monitoring plan would serve as an internal mechanism for quality assurance, quality improvement and education pursuant to research billing compliance.

Recommendation

We recommend Billing Compliance establish an implementation date for commencing clinical trials billing compliance monitoring. Additionally, the clinical trials billing compliance plan, which includes monitoring areas, should be finalized and formally approved. Monitoring activities should be scheduled and conducted in accordance with policies. Quality reviews should target high risk areas and results should be discussed with appropriate research department members. Follow-up reviews should be conducted based on assigned scores and necessary corrective steps taken. Billing Compliance should ensure resources are allocated to ensure clinical trials billing compliance monitoring occurs.

Management Response

A draft Research Billing Compliance Plan, which addresses clinical trials billing, has been developed. This Plan will include a section that establishes the specific monitoring plan for clinical trial services. The Research Billing Compliance Plan will be reviewed by the University and Professional Billing Compliance Committee (UPBCC) at its February 2013 meeting. Formal, separate (from current Practice Plan and University Hospital billing activities) monitoring of clinical trials billing activities will be implemented in calendar year 2013.

Implementation Status: In Process
Implementation Date: March 31, 2013

Responsible Personnel:
Director, Billing Compliance

4. Clinical Trials and Research Policies

Clinical Trials and Research policies have not been updated in recent years and need revision, addition or expansion. Policies in need of updating are as follows.

Responsible Area	Policy
a. Research Administration	RES-151 Institutional Review Board for Human Research (1) RES-202 Standards of Care and Use of Laboratory Animals (2) RES-251 Grants Management (3) RES-252 Clinical Trials (1) RES-304 Confidential Disclosure Agreements (shared between Research Administration and Office for Technology Development) (1)
b. Medical Center Policy Office (under discussion for assigning to Research Administration)	RES-101 Misconduct or Fraud in Research (3)
c. Vice Provost and Dean of Basic Research	RES-201 Animal Resources Center (2)
d. Formerly with the Office of Contracts Management now under the Office for Technology Development	RES-301 Sponsored Research Agreements (3) RES-302 Collaborative Research Agreements (3) RES-303 Material Transfer Agreements (3)
e. Office for Technology Development	RES-351 Bioinstrumentation Resources Center (3)

Applicable to:
(1) - Human Subject Research
(2) - Non-Human Subject Research
(3) - Both Human and Non-Human Subject Research

Updated policies guide decisions and actions in the accomplishment of institutional goals. Further, an objective of Research Administration is to continue planning for obtaining accreditation with the Association for the Accreditation of Human Research Protection Program or AAHRPP. This process requires organizations to provide tangible evidence through policies, procedures, and practices of their commitment to scientifically and ethically sound research and to continuous improvement.

Policies represent a documented set of basic principles formulated and enforced by the governing body of an institution to guide decisions, direct and limit its actions in pursuit of long-term goals. Policies governing Medical Center research and sponsored programs are outlined in the Handbook of Institutional Policies and

Operating Procedures. These policies provide guiding principles in the management of research, prohibition of misconduct, fraud, or conflicts of interest, and commitment to compliance.

Recommendation

We recommend the offices providing research administrative services collaborate to establish a timeline to update the Research policies to reflect the mission and goals of the institution, management expectations and pertinent changes to rules and regulations. The accreditation processes include the completion of a readiness self-assessment by the institution to remedy any program weaknesses, and to determine that written documents are meeting applicable accreditation standards. Action plan steps should be established to ensure the accomplishment of stated goals.

Management Response

a. Research Administration - Research Policies will be reviewed and updated as part of the next wave for the Executive Policy Committee. Research Administration has met with the Policy Office; a plan is in development by the respective divisions in Research Administration and will be associated with the target goals of the divisions for fiscal year 2012-2013.

b. Medical Center Policy Office - Responsibility is under discussion for assigning to Research Administration. For purposes of this audit and until the final determination concerning this policy area can be set, the Vice President for Research Administration will assume responsibility to have the policy updated and implemented as part of the policy set identified in Section a above.

Implementation Status: In Process
Implementation Date: August 31, 2013

Responsible Personnel:
Vice President, Research Administration

c. Vice Provost and Dean of Basic Research - We have submitted an updated draft of Policy RES-201 to the Policy Office for final approval.

Implementation Status: Implemented
Implementation Date: September 5, 2012

Responsible Personnel:
Vice Provost and Dean of Basic Research

d & e. Office for Technology Development - We will update the following policies by the end of February:

RES-301 Sponsored Research Agreements
RES-302 Collaborative Research Agreements
RES-303 Material Transfer Agreements
RES-304 Confidential Disclosure Agreements (shared with Research Administration)

Bioinstrumentation ceased operations on December 15, 2011; therefore, RES-351 Bioinstrumentation Resources Center will be deleted.

Implementation Status: In Process
Implementation Date: February 28, 2013

Responsible Personnel:
Director, Office for Technology Development

Conclusion

Overall, the Research Administration Office has developed the elements of a research compliance program that adequately monitor and manage the Medical Center's high risks in research, with the exception of clinical trials billing compliance which is in process.

In order to enhance controls in the management of risks associated with clinical trials billing compliance, we made recommendations related to 1) CTF Support Function - finalization of the organizational structure and staffing level of the CTF support function; 2) Clinical Trials Compliance Training - continued collaboration to determine necessary clinical trials billing compliance training requirements, to obtain policy approval and training budget approval and identification and enrollment of department personnel required to complete compliance training; 3) Clinical Trials Billing Compliance Monitoring - obtain approval for the Research Billing Compliance Plan, which includes clinical trials billing compliance monitoring, and ensure resources are allocated to ensure clinical trials billing compliance monitoring occurs; and 4) Clinical Trials and Research Policies - coordinate with the responsible offices in updating the Clinical Trials and Research Policies outlined in the Handbook of Institutional Policies and Operating Procedures to ensure accomplishment of stated goals and missions.

We appreciate the courtesy and cooperation of all staff within the Research Administration Office and the Office of Compliance.

Andrea Claire, JD, MBA, CIA	- Manager of Internal Audit
Van Nguyen, CPA	- Supervisor of Internal Audit
Aaron Munoz, CIA, CGAP, MPA	- Senior Auditor

450 Audit Hours Expended

Sincerely,

Eva Narten

Eva Narten, CPA, CIA, CISA
Assistant Director of Internal Audit

Cc:	Arnim E. Dontes, MBA	Executive Vice President for Business Affairs
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