UNIVERSITY OF
TEXAS
ARLINGTON

RESEARCH COMPLIANCE REVIEW

OCTOBER 09, 2012

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UNIVERSITY OF TEXAS ARLINGTON | INTERNAL AUDIT

MEMORANDUM

TO: James D. Spaniolo
President

FROM: Ken Schroeder
Director of Internal Audit

DATE: October 10, 2012

SUBJECT: Research Compliance Review Report Dated October 09, 2012

Executive Summary

As part of FY 2012 audit plan, we have completed a review of Research Compliance. The objective of the audit was to determine whether a compliance program has been implemented to manage risks in the institution's functional research areas (FRAs). The FRAs chosen for review were human subjects, animal subjects, recombinant DNA, export controls, technology transfer, and grants and contracts.

In our opinion, the FRAs have procedures and practices in place to effectively manage and monitor activities for compliance and internal control. Compliance practices include, but are not limited to, policies, procedures and compliance activities that are embedded within the daily, monthly and quarterly responsibilities of research personnel. Additionally, appointment of a responsible official for each FRA along with the training provided for research staff further ensures an effective program.

We appreciate the courtesy and cooperation we received from Research Administration throughout this audit. If you have any questions, please contact me at extension 2-2018.

cc: Dr. Ronald L. Elsenbaumer, UT Arlington, Provost and Vice President for Academic Affairs
Ms. Kelly Davis, UT Arlington, Vice President for Business Affairs and Controller
Mr. John Hall, UT Arlington, Vice President for Administration and Campus Operations
Dr. Carolyn Cason, UT Arlington, Interim Vice President for Research
Mr. Jeremy Forsberg, UT Arlington, Assistant Vice President for Research
Ms. Kirstin Morningstar, UT Arlington, Director, Regulatory Services
Ms. Sarah Panepinto, UT Arlington, Director, Grant and Contract Services
Ms. Natalia Toth, UT Arlington, Assistant Director, Office of Technology Transfer
Ms. Jennifer Chapman, UT Arlington, Executive Director Compliance Services
Dr. Pedro Reyes, UT System, Executive Vice Chancellor for Academic Affairs
Mr. Alan Marks, UT System, Attorney – General Law Section
Mr. J. Michael Peppers, UT System, Chief Audit Executive *ad interim*
Ms. Moshmee Kalamkar, UT System, Audit Manager
Mr. Ed Osner, Legislative Budget Board
Mr. Michael Sparks, Governor's Office of Budget, Planning and Policy
Internal Audit Coordinator, State Auditor's Office
Mr. Joey Longley, Sunset Advisory Commission

Background Information

At the request of UT System, all academic institutions were to determine whether significant research compliance areas are adequately monitored and managed to reduce and control research risks. Through discussions with Research Administration, the significant FRAs (right) were identified for review.

Functional Research Areas (FRAs)

1. Human Subjects
2. Animal Subjects
3. Recombinant DNA
4. Export Controls
5. Technology Transfer
6. Grants and Contracts

Objectives

The objective of the audit was to determine whether a compliance program has been implemented to manage risks in the institution's functional research areas (FRAs).

Scope and Methodology

Our examination was conducted in accordance with guidelines set forth in the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing* and *Generally Accepted Government Auditing Standards.* The *Standards* set criteria for internal audit departments in the areas of independence, professional proficiency, scope and performance of audit work, and management of the internal auditing department. UTS 129 titled "Internal Audit Activities," require that we adhere to the *Standards.*

The audit scope was limited to the FRAs identified above for processes and procedures in effect as of August 2012. Questionnaires were developed for each of the significant FRA's and the completed questionnaires were reviewed. The questionnaires covered numerous topics such as whether there was appropriate assignment of responsibility, risk assessment, compliance monitoring, and compliance education. There were no significant issues from the results of the questionnaire review.

Review Results

Institutional Official and Oversight Committees

The Institutional Official responsible for monitoring compliance for human subjects, animal subjects, and recombinant DNA is the Provost. Oversight responsibilities are delegated to the Institutional Review Board – for Human Subjects; Institutional Animal Care and Use Committee – for Animal Subjects; and Institutional Biosafety Committee – for Recombinant DNA. The Office of Regulatory Services personnel are very involved in ensuring that pertinent information is brought before these committees, and that regulatory requirements are complied with.

In the other research areas, the daily operations and oversight responsibilities are assigned to the Assistant Vice President for Research Administration and the Directors. No issues were noted in our review of responsibility assignment for compliance matters.

Risk Assessment

University Compliance Services facilitated a level 2 review of risks with Research Administration management on March 8, 2011. An insufficient staffing level was listed as a high risk at that time. Research Administration management continues to assess this as a significant risk but not to the extent that existed in 2011, as some additional staff has been hired to reduce the risk. Although the above listed FRAs are significant aspects of UT Arlington's research, management believes that the risks are below a "high risk" rating. Additionally, Research Administration management believes that the FRAs are well managed by the responsible departments. Through our reviews in each of the above FRAs, we noted that compliance activities and monitoring are in place and there were no significant issues noted in our review.

Monitoring

Questionnaires were created covering the FRAs to determine the level of research compliance or if compliance monitoring was being done. The responses were reviewed and validated with responsible research personnel for the FRA. The Institutional Official, Oversight Committees, Assistant Vice President for Research Administration and the Directors all contributed to monitoring and compliance activities for the research areas -- through policy and procedures, embedded compliance activities, and reporting. Also, external parties evaluate the research areas to provide an additional level of compliance. An example of this is the accreditation of the animal subject program scheduled for November 2012 by the Association of Assessment and Accreditation of Laboratory Animal Care (AAALAC). We found that the FRAs have implemented compliance and monitoring programs and no issues were noted.

Research Compliance Education

Research Administration provides a number of specialized training venues to research staff routinely throughout the year to ensure compliance with policies, procedures, and grant and contract terms. Examples of such training are:

- Profile system training (a web-based tool for research electronic applications)
- Online training
- Face-to-face training
- Webinars
- Educational training conferences
- Informational training sessions at meetings
- Hands-on training
- Orientation in the laboratories

Principal Investigators, Oversight Committee members, The Office of Regulatory Services, and Grant and Contract Services staff all receive training. In the event compliance monitoring activities discloses any non-compliance issues, additional training is provided to those involved

to ensure compliance. Compliance education for research staff is being practiced and no issues were noted through our reviews.

Conclusion

In our opinion, the FRAs have procedures and practices in place to effectively manage and monitor activities for compliance and internal control. Compliance practices include but are not limited to policies, procedures and compliance activities that are embedded within the daily, monthly and quarterly responsibilities of research personnel. Additionally, appointment of a responsible official for each FRA along with the training provided for research staff further ensures an effective program.

We appreciate the courtesy and cooperation we received from Research Administration throughout this audit.