Audit Report # 13-06
April 18, 2013

Office of Auditing and Consulting Services

"Committed to Service, Independence and Quality"
April 18, 2013

Dr. Diana Natalicio  
President, University of Texas at El Paso  
Administration Building, Suite 500  
El Paso, Texas 79968

Dear Dr. Natalicio:

The Office of Auditing and Consulting Services has completed a limited-scope audit of the University’s Research Compliance Program. The main audit objective was to determine whether an institutional-wide compliance program has been implemented to manage the high risk research areas to include, but not limited to, Human Subject Research, Animal Research, Laboratory Safety, and Responsible Conduct of Research.

We appreciate the cooperation and assistance provided by the management and staff of the Office of Research and Sponsored Projects, Environmental Health & Safety, and the Office of Institutional Compliance.

Sincerely,

[signature]

William A. Peters, CPA, CIA  
Director
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University of Texas at El Paso

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EXECUTIVE SUMMARY

The audit of the Research Compliance Program at The University of Texas at El Paso was conducted at the request of The University of Texas System. The purpose of the audit was to evaluate the design of the institution's research compliance program and to determine whether it encompasses the key elements of an Effective Compliance Program as defined by the Federal Sentencing Guidelines Manual.

Human Subject Research, Animal Research, Laboratory Safety, and Responsible Conduct of Research were high risk areas identified and selected for the audit. Effort Reporting, Conflict of Interest, Technology Transfer, and Export Controls are also considered high risk research areas at the University; however, these areas will be included in audits scheduled later in this fiscal year.

During the audit, we noted:

- Post approval monitoring for Human Subject Research projects is not conducted at the University.
- UTEP joined the "Collaborative Institutional Training Initiative", a web-based training site to provide all research-related compliance training to UTEP's research community in 2012. The notification/tracking system for the Responsible Conduct of Research module is currently being refined by the Office of Research and Sponsored Projects to ensure timely notification to all applicable employees of their training needs.

With the exceptions noted above, we conclude that the basic elements for an effective Research Compliance Program for Animal Research, Human Subject Research, Laboratory Safety, and Responsible Conduct of Research are in place.
BACKGROUND

The Texas Higher Education Coordinating Board has designated UTEP as one of the emerging Tier One universities because of its significant progress in acquiring, developing and utilizing research capacity and expansion of its doctoral programs.

To ensure that proper administration and controls are in place to support the University’s research projects, a strong compliance program is necessary. According to the Association of College and University Auditors, the Federal Sentencing Guidelines (FSG) Manual for an Effective Compliance Program has become the standard by which most institutions measure their own compliance oversight programs. Chapter 8 of the FSG states:

§8B2.1 (b)(1)(a) To have an effective compliance and ethics program an organization shall
(1) exercise due diligence to prevent and detect criminal conduct; and
(2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.

The FSG recommended compliance program includes the following elements:

1. Written standards, policies and procedures
2. Designation of a compliance officer and compliance committee
3. Definition of Roles and Responsibilities
4. Effective lines of communication
5. Effective training programs
6. Monitoring and auditing
7. Prompt response and corrective action to detected problems
AUDIT OBJECTIVE

The objective of this audit was to evaluate the design of the institution’s research compliance program and to determine whether it encompasses the key elements of an Effective Compliance Program as defined by the Federal Sentencing Guidelines (Guidelines). The research areas included in the audit are:

- Human Subject Research
- Animal Research
- Laboratory Safety
- Responsible Conduct of Research

Effort Reporting, Conflict of Interest, Technology Transfer, and Export Controls are also considered high risks research areas and will be addressed individually in future audits.

SCOPE AND METHODOLOGY

The audit scope was limited to activities related to the UTEP Research Compliance Program for the four selected high risk research areas from September 1, 2011 to December 31, 2012. Audit procedures included interviewing key personnel, reviewing applicable regulations, and verifying the existence of appropriate institutional policies and procedures.

The audit was conducted in accordance with the International Standards for the Professional Practice of Internal Auditing issued by the Institute of Internal Auditors.
AUDIT RESULTS

We assessed each of the compliance elements summarized in the table below to determine whether the UTEP Research Compliance Program contains the basic elements of an Effective Compliance and Ethics Program according to the Guidelines.

<table>
<thead>
<tr>
<th>Compliance Element</th>
<th>Human Subject Research</th>
<th>Animal Research</th>
<th>Laboratory Safety</th>
<th>Responsible Conduct of Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Written standards, policies, and procedures</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>2 Designation of a compliance officer and a compliance committee</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>3 Definition of roles and responsibilities</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>4 Effective lines of communication (Includes confidential reporting mechanism &amp; hotlines)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>5 Effective Training Programs</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>6 Monitoring &amp; Auditing (Includes reporting)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>7 Prompt response and corrective action to detected problems</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**LEGEND:**  
I Implemented  
IP In Progress
The basic elements for an effective Research Compliance Program for Animal Research, Human Subject Research, Laboratory Safety, and Responsible Conduct of Research are in place with the following exceptions:

- Post approval monitoring for Human Subject Research projects is not conducted at the University.
- The new notification/tracking system for Responsible Conduct of Research was implemented in September 2012 and it is currently being refined to ensure timely notification to PIs of training needs.

Compliance Element 1 Written Standards, Policies, and Procedures

*The organization shall establish standards and procedures to prevent and detect criminal conduct. §8B2.1(b)(1)*

According to the UTEP Handbook of Operating Procedures (HOOP), all UTEP employees must pass a criminal background check as part of the hiring process. Extensive testing of timely employee and student background checks was performed during a recent Human Resource Services audit. No exceptions were noted.

Animal Research

HOOP, Section IV, Chapter 8 *Care, and Use of Animals in Research and Teaching* offers information regarding applicable provisions for the care and use of animals in research and teaching. The veterinarian and his staff maintain a Standard Operating Procedures Manual that addresses specific tasks such as the daily care and monitoring of laboratory animals. Additional written procedures are provided in the Institutional Animal Care and Use Committee Guidebook.

Human Subject Research

HOOP, Section IV, Chapter 3 *Policy for Review of HSR* provides guidance for compliance with federal regulations (45 CFR 46) for the protection of human subjects. Specific Human Subject Research policies and procedures for Case Study and Classroom Research are published on the HSR webpage, including decision trees and research project checklists for proper IRB protocol development and submission.

Laboratory Safety

HOOP, Section VIII, Chapter 1 *Environmental Health & Safety (EHS)*, provides recommendations for safe conduct in laboratory settings. The EHS web page also includes detailed policies, procedures, and manuals for high risk research areas and individual research laboratories.

Responsible Conduct of Research

The UTEP Office of Research and Sponsored Projects (ORSP) publishes a Responsible Conduct of Research (RCR) Training Policy on the ORSP website which outlines the CITI program, a subscription service providing research ethics education to all members of the research community.
Compliance Elements 2-3 Compliance Officer and Roles & Responsibilities
High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program, as described in this guideline. Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program. §8B2.1(b)(2)(C)

Specific roles for the UTEP Research Compliance Program are assigned to designated responsible parties who oversee specific research areas, including monitoring and training responsibilities. All parties report directly to the Vice President for Research and Sponsored Projects.

Compliance Element 4 Communication (Hot Lines, Complaints)
The organization shall take reasonable steps... to have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization’s employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation. §8B2.1(b)(5)(C)

The UTEP Office of Institutional Compliance (OIC) monitors an anonymous compliance helpline. Complaints and concerns may also be reported anonymously via e-mail, walk in, direct call, web, or during exit interviews. The Human Resource Services exit interview questionnaire specifically asks the departing employees if they were aware of any ethical or compliance concern in the job or work environment. Section V of the HOOP provides further guidance.

Compliance Element 5 Training
The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subparagraph (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals’ respective roles and responsibilities. §8B2.1(b)(4)(A)

Animal Research
HOOP, Section IV, Chapter 8 states that the Institutional Animal Care and Use Committee (IACUC) is responsible for ensuring that research personnel are appropriately qualified and trained to perform any procedures relating to animals. Training includes completion of the American Association of Laboratory Animal Science (AALAS) Learning Library Modules (aalaslearnlibrary.org), applicable Environmental Health and Safety (EH&S) Training, and Veterinary Services Vivarium training.

Human Subject Research
HOOP, Section IV, Chapter 3 requires all UTEP researchers (faculty, staff and students) conducting IHSR (intervention and/or interaction) to complete IHSR ethics training. Collaborative Institutional Training Initiative (CITI) was also implemented in September 2012 for ethical conduct in conducting human subjects’ research, and Social and Behavioral modules (SBR) as educational requirements for the Institutional Review Board (IRB) at UTEP. CITI provides more
comprehensive training modules placing an emphasis on ethical conduct when human participants are involved. Researchers involved with human subjects’ research are required to take a minimum of sixteen modules, all focusing on a different aspect of research topics.

Laboratory Safety
HOOP, Section VIII, Chapter 1 describes UTEP’s Environmental Health and Safety Department’s training programs to help the University community understand general campus safety issues and recognize the specific hazards within their work or environment. Training programs include radiation safety, hazardous chemical training, biological safety, loss prevention and emergency preparedness. In addition EH&S maintains a database of laboratory employees that includes the corresponding training requirements and completion status.

Responsible Conduct of Research
Utilizing the web-based CITI software, UTEP has identified and established a specific RCR curriculum by discipline (Biomedical, Social & Behavioral Research, Physical Sciences, Humanities, Engineers, and Administrators). The RCR topics through CITI include Research Misconduct, Data Management, Conflict of Interest, Collaborative Science, Responsible Authorship, Mentoring, Peer Review, Research with Animal Models and Protections of Human Subjects in Research.

Compliance Element 6 Auditing and Monitoring
The organization shall take reasonable steps to ensure that the organization’s compliance and ethics program is followed, including monitoring and auditing, to detect criminal conduct to evaluate periodically the effectiveness of the organization’s compliance and ethics program. §8B2.1(b)(5)(A)

Animal Research
Animal Research has implemented a program to audit and monitor departmental operations. The responsibilities of the IACUC include the review, at least once every six months, of the institution’s animal care program, including a physical inspection of the facilities in accordance with the Guide for the Care and Use of Laboratory Animals. A Recent Animal Research audit determined that the Semiannual Evaluation of Animal Care and Use Program and Inspection of Facilities Reports were performed every six month per Public Health Services policy. IACUC has developed a timeline to use as a checklist to ensure timeliness and completeness of reports and follow-up actions.

Human Subject Research
The process for the review and approval of all HSR protocols is appropriately monitored. The Institutional Review Board (IRB) is responsible for protecting human subjects who participate in research. All review procedures meet or exceed the requirements set forth in 45 CFR 46. The IRB provides review and oversight for all human subject research activities performed on the campus. The IRB has adopted IRBNet, a web based set of electronic tools to support the
management, submission, review and oversight of research protocols; however, no post-approval monitoring for Human Subject Research projects is conducted at the University.

**Recommendation:** ORSP should develop a formal post-approval monitoring plan to provide adequate oversight for human research activity.

**Management Response:** In light of this audit, the human subjects’ area is in the process of developing a post-approval monitoring (PAM) plan.

**Responsible Party:** Antonio Woo, Assistant Vice President for Research and Athena Fester, IRB Administrator, Research and Sponsored Projects.

**Implementation Date:** January 2014

**Laboratory Safety**
EH&S has implemented programs to audit and monitor laboratory safety to ensure compliance with prudent laboratory practices, National Institute of Health Guidelines, requirements of the Center for Disease Control, U. S. Department of Homeland Security, and the Texas Health and Safety Code. Lab inspections are conducted according to an annual scheduling plan. Safety violations are communicated to the department and follow-up inspections are scheduled to determine if recommendations have been implemented timely.

**Responsible Conduct of Research**
The notification/tracking system for the Responsible Conduct of Research module was implemented in September 2012 and it is currently being refined to ensure timely notification to all applicable employees. The Office of Research and Sponsored Projects has developed a tool for notification, tracking, and monitoring of completion status. At the time of employee appointment and/or award notification, data is collected in the CITI administration tool. An initial notification is issued informing the individual that the RCR training must be completed within 30 days of notification. A reminder notice is issued within 10 days thereafter, and a second reminder notice is sent to the individual and the appropriate supervisor 10 days thereafter. On the 60th day, a third "delinquency" notice is issued to chairs, deans, and UTEP leadership.

**Additional Institutional Auditing and Monitoring Activities**
The Office of Auditing and Consulting Services, in collaboration with the Office of Institutional Compliance, prepares an annual risk assessment which includes an evaluation of the institution’s risk exposures including research compliance. The risk assessment and the audit plan are approved annually by the UTEP Audit Committee. A risk management plan is developed for every business process identified as high risk, and a responsible party is assigned to manage the risk. Monitoring activities are reported to the Executive Compliance Committee on a quarterly basis, as are instances of non-compliance.
Compliance Element 7 Prompt Response to Detected Problems
After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization’s compliance and ethics program. §8B2.1 (7)

HOOP, Section IV, Chapter 6 contains a Research Misconduct Policy Statement to address non-compliance. Suspected violations should be reported to the Vice President of ORSP, who conducts investigations to determine the appropriate corrective actions, which may include self-reporting compliance violations to federal and state agencies.

CONCLUSION

Based on the results of audit procedures performed, we conclude that the compliance elements are in place for the research programs audited; however, we believe that the auditing and monitoring functions can be strengthened by implementing the recommendations detailed in this report.

We wish to thank the staff at the Offices of Animal Research, Human Subject Research, Environmental Health and Safety, the College of Health Sciences, and the ORSP for their assistance throughout the audit.