PROJECT SUMMARY

Overview

Overall, the controls established over the Human Subjects’ Protection Program at Texas A&M University are generally effective in providing reasonable assurance that the University is operating in compliance with applicable federal laws and guidelines, System regulations and University rules, except in the area of timely reporting of approved expedited protocols to the Institutional Review Board (IRB). Opportunities for improvement were also identified in the areas of monitoring the completion of human subject research training, performance measurement, and database development. During fiscal year 2009, the Human Subjects’ Protection Program received 1,553 protocols for processing.

Over the last year, the Offices of Research Compliance, Biosafety and the Comparative Medicine Program have increased their staff and expanded their responsibilities, augmenting the need for long-term funding of these offices.

Summary of Significant Results

Protocol Tracking and Reporting

Human Subjects’ Protection Program staff did not identify that for more than two years, 38% of approved expedited protocols were not reported to the IRB as required. This was due to staff relying on a system generated report which did not include all expedited protocols as a result of an undetected software problem caused by a system upgrade in August 2007. Upon being made aware of this oversight by the audit team, staff reported the problem to the IRB on December 18, 2009. Over five months later on May 24, 2010, a required report was sent to the federal Office for Human Research Protections (OHRP).
Summary of Management’s Response

The Office of the Vice President for Research and Graduate Studies has reviewed the audit findings and concurs with recommendations for improvement to the Human Subjects’ Protection Program at Texas A&M University.

Detailed responses are described in each of the following sections.

Scope

The review of the Human Subjects’ Protection Program within the University’s Office of the Vice President for Research and Graduate Studies focused on activities for the period September 1, 2008 through August 31, 2009. The Institutional Review Board is administered by the Human Subjects’ Protection Program. Additionally, research compliance databases and overall funding of the Offices of Research Compliance and Biosafety and the Comparative Medicine Program were also included in the review. Fieldwork was conducted from October 2009 to March 2010.
OBSERVATIONS, RECOMMENDATIONS, AND RESPONSES

1. Protocol Tracking and Reporting

Observation

From August 2007 to November 2009, 725 of 1,924 expedited protocols (38%) were not reported to the Institutional Review Board (IRB) members. The error was caused by an August 2007 software update to InfoEd, the software program used to track research projects and protocols. The upgrade caused an undetected change to InfoEd’s report parameters. Management was not analyzing the accuracy of the data and did not detect the error. Upon being made aware of this oversight by the audit team, the Human Subjects’ Protection Program reported the situation and the missing expedited protocols to the IRB on December 18, 2009. Over five months later on May 24, 2010, a required report was sent to the federal Office for Human Research Protections.

The Code of Federal Regulations, Title 45, Part 46.110 (c) states that, “Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.” Sections 46.103(a) and 46(b)(5) require that institutions have written procedures to ensure that instances of continuing noncompliance with the policy or the requirements or determinations of the IRB are “promptly” reported to the federal Office for Human Research Protection. On May 27, 2005, the Office of Human Research Protections issued a document titled “Guidance on Reporting Incidents to OHRP” that provides guidance on what is meant by “promptly.” It states that for less serious incidents, a few weeks may be a sufficient reporting time.

While written procedures were in place detailing how expedited reviews are to be processed and reported monthly to the IRB, the electronic reporting mechanism was not working as intended. Failures to notify the IRB of all the expedited protocols and to promptly notify the Office for Human Research Protection of this nonreporting resulted in the University being in noncompliance with federal regulations.
1. Protocol Tracking and Reporting (cont.)

**Recommendation**

Ensure IRB members are notified in a timely manner of all proposals approved with expedited reviews. Periodically review reports created in the InfoEd database to ensure the reports are accurate, especially after updates have been made to the program. Develop a process to ensure that any future instances of noncompliance are promptly reported to the federal Office for Human Research Protections.

**Management’s Response**

Management concurs with the recommendations. The Human Subjects’ Protection Program (HSPP) immediately corrected InfoEd so that reports were accurate. InfoEd generated reports are now reviewed on a periodic basis to ensure their accuracy. HSPP management has implemented manual documentation of IRB notification on protocol files to ensure expedited approval has been sent to the IRB. The procedures for reporting instances of noncompliance to the federal Office for Human Research Protections is under review and will be modified to ensure full compliance with relevant requirements.

*Implementation date: August 31, 2010.*

2. Monitoring of Required Training

**Observation**

The Human Subjects’ Protection Program does not track or receive notification when a principal investigator's required training will expire. Prior to receiving IRB approval, principal investigators are required by the University’s standard operating procedures to pass a web-based training course provided by an external vendor on conducting human subject research. Principal investigators must also pass a refresher course every two years thereafter. The vendor sends advance notification to the principal investigator when their training is going to expire. The Human Subjects’ Protection Program has access to the training database; however, they only check training records at the time a protocol is submitted for initial or continuing review as specified in its standard operating procedures. Therefore, an investigator's required human subject training could expire after the protocol is approved and the Human Subjects’ Protection Program might not know that the training has expired for up to a year. Staying current on required training helps to ensure that principal investigators are aware of applicable
2. Monitoring of Required Training (cont.)

| federal laws and ensures their compliance with the University’s standard operating procedures. |

Recommendation

Implement procedures to ensure that the Human Subjects’ Protection Program is aware of the lapse of required training for any principal investigators with active human subject protocols.

Management’s Response

Management concurs with the recommendation. A procedure has been put in place to ensure compliance with training requirements. Notifications are sent to principal investigators by the CITI training software 90 days prior to training expiration reminding them to complete the required refresher course. HSPP management will send an additional notice 30 days prior to training expiration (as needed) to principal investigators reminding them to complete the refresher course. If training expires, for any investigator, the approval/exemption will be suspended until training has been updated. In addition, an outreach campaign has been initiated to ensure all principal investigators are aware of their training requirements.

Implementation date: August 31, 2010.

3. Performance Measures

Observation

The Human Subjects’ Protection Program does not have fully developed performance measures. The program has established some estimates in their standard operating procedures regarding processing times, but the program’s performance on these estimates is not tracked. Absence of goals, objectives, and performance measures increases the risk that executive management cannot hold departments accountable for their performance, particularly as departments experience growth.

Performance measures provide management with a tool for reviewing operations and identifying areas for improvement. Additionally, a good performance measurement system provides information that is meaningful and useful to decision-makers and is an integral part of the daily operations.
Recommendation

3. Performance Measures (cont.)

| Develop performance measures for the Human Subjects’ Protection Program to help ensure the program performs effectively and in compliance with standard operating procedures. |

Management's Response

| Management concurs with the recommendations. While the HSPP has tracked processing times for each major step in the intake and processing, review, and approval processes for each submission type, the program did not compare actual performance against estimated processing times. Performance measures given in standard operating procedures will be reviewed and revised, if needed, by HSPP management. In addition, procedures will be put in place to ensure these measures are tracked and reported on a timely basis by management. |

| Implementation date: August 31, 2010. |

4. Database Needs Assessment

Observation

**A research compliance database needs assessment should be completed.**

The Office of Research Compliance has initiated but not yet completed a database needs assessment as part of the development of a new research administration system. A Texas A&M University System initiative is under way to develop an integrated electronic research administration system that will be used by System research institutions based in the Bryan-College Station area. The system is based on Texas Engineering Experiment Station’s in-house developed research administration system and is known as Maestro (Modular Application for the Electronic Submission and Tracking of Research Operations). Phase I, creation of a central data repository, is almost complete with Phase II, Pre-Award, set to begin the final scoping process in June 2010. One of the proposed processes for Phase II includes electronically tracking regulatory compliance measures which involve the Office of Research Compliance. Currently, no one from Research Compliance is attending the Maestro meetings.

The Office of Research Compliance has not completed the database needs assessment for Phase II of Maestro mainly due to turnover in personnel and organizational changes. A thorough evaluation of protocol management needs should be performed and included in the scoping process for Phase II of Maestro. A
4. Database Needs Assessment (cont.)

formal needs assessment involving all user groups is necessary before any software solution can be thoroughly analyzed. If funding or sufficient staff time does not exist to include the Office of Research Compliance’s needs, then alternatives should be sought.

Recommendation

Complete a thorough research compliance database needs assessment. Ensure that these needs are presented to the Maestro steering committee. Consider appointing someone from Research Compliance to attend the Maestro meetings. If funding or staffing constraints prevent protocol management from being included in Phase II then Research Compliance should develop long-range plans for addressing its database needs.

Management’s Response

Management concurs with the recommendations. Office of Research Compliance has accelerated its research compliance database needs assessment and will ensure that results are presented to the Maestro steering committee. Furthermore, the Office of the Vice President for Research and Graduate Studies will ensure a representative of the Office of Research Compliance attends Maestro meetings.

Implementation date: August 31, 2010.

5. Funding Issues

Observation

The University is subsidizing funding of research compliance for other System members.

The Offices of Research Compliance and Biosafety perform services for Texas A&M University as well as various other System members. The Office of Research Compliance is not being directly compensated by the other System members for these services. Other System members contribute faculty to sit on various compliance boards but do not contribute funds to support the boards’ administrative activities and functions. The Office of Biosafety receives some funding from other System members; however, the Office of the Vice President for Research and Graduate Studies does not feel that it is proportionate to the cost of the biosafety services provided. Discussions are under way with various System members and, while all are agreeable to contribute funds, actual amounts and funding mechanisms have not been determined.
5. Funding Issues (cont.)

Additionally, the University’s Comparative Medicine Program operates as a service center; however, the current rates charged for its services do not cover its costs. In fiscal year 2010, the Office of the Vice President for Research allocated approximately $1.4 million (39% of the program’s $3.6 million budget) to help cover the operations of the Comparative Medicine Program. System regulation states that service center billing rates should be designed to recover the direct operating costs of providing services and internal support costs, on an annual basis. During the fall of 2009, Comparative Medicine Program staff began working with the Division of Finance to develop new rates that would allow for full cost recovery.

**Recommendation**

Complete the review of the Comparative Medicine Program rate structure and develop a methodology for sharing the cost of research compliance administration with the other System members utilizing the services.

**Management’s Response**

*Management concurs with the recommendations.*

*The Office of the Vice President for Research and Graduate Studies will, along with System stakeholders, develop a methodology for sharing the cost of biosafety and research compliance administration with other System members. Once a methodology has been determined, a written agreement between System stakeholders will be put in place which outlines cost sharing and effective dates.*

*Implementation dates:*
Methodology for cost sharing: November 30, 2010.
Written agreement in place: February 2011.

*The Office of the Vice President for Research and Graduate Studies is in the process of reviewing the Comparative Medicine Program rate structure. A new Executive Director of the Comparative Medicine Program is expected to start August 1, 2010 and his input into the rate structure is critical. Once a rate structure has been developed, a communication plan to inform stakeholders will be executed in advance of any changes to the rates. Data to determine specific rates will be collected starting September 1, 2010. Once six months of data has been collected, it will be analyzed to determine the actual rates charged to users.*
5. Funding Issues (cont.)

**Implementation dates:**
- Implementation of revised user rates: September 1, 2011.
BASIS OF REVIEW

Objective

Review research compliance at the University to determine if resources are used efficiently and effectively and in compliance with laws, policies, regulations, and University rules. During the planning process, the scope was narrowed to focus on the Human Subjects’ Protection Program as well as the research compliance database and overall funding of research compliance.

Criteria

Our audit was based upon standards as set forth in the System Policy and Regulation Manual of the Texas A&M University System and other sound administrative practices. This audit was performed in compliance with the Institute of Internal Auditors’ “International Standards for the Professional Practice of Internal Auditing.”

Additionally, we conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human subjects or patients recruited to participate in research activities, regardless of the source of funding. The IRB reviews research protocols to ensure that the rights and welfare of subjects are protected and that the proposed use of human subjects is in compliance with federal, state, and Texas A&M University rules and procedures. The IRB is administratively located in the University’s Office of the Vice President for Research and Graduate Studies under the Human Subjects’ Protection Program. During fiscal year 2009, the Human Subjects’ Protection Program received 1,553 protocols. These consisted of 77 for full board review, 849 for expedited review, and 627 for exempt review.
Also under the Vice President for Research and Graduate Studies is the Comparative Medicine Program. This program is the centrally-administered support service for animal research and teaching programs at Texas A&M University in College Station, Texas.
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