Overall Conclusion

Currently, the Human Subjects Protection Program (HSPP) at Texas A&M University has been able to maintain processes and controls to demonstrate compliance with most of the laws and policies governing human subject research compliance. However, the loss of any HSPP employee could significantly impact the operation of the program. Staffing levels within the HSPP need to be reassessed, particularly given the importance within the A&M System for growth in research funding and the establishment of a strong culture of compliance. Additionally, even though indicated as implemented, the university continues to need to address two prior audit issues from 2010 including improving its compliance with required human subject research training and establishing performance targets for the HSPP’s performance measurement system. Other opportunities for improvement were noted in the areas of human subject research at the new Texas A&M School of Law, conflict of interest disclosure statements, and disaster recovery planning for the web-based research compliance management system (iRIS).

The university’s HSPP provides human subject research compliance services for most A&M System members located in the Brazos Valley.

Summary of Significant Results

Program Staffing and Efficiency

At current staffing levels, the volume of human subject research applications submitted to the HSPP increases the risk of noncompliance with human subject research requirements. HSPP staff consists of three coordinators plus an HSPP manager and post approval monitor. During the 11-month period from January to November 2013, more than 2,500 applications (230 applications per month) were submitted to the HSPP for review. The extent of time required to process and review applications has greatly limited the amount of time the HSPP staff can devote to other assigned duties important to maintaining the effectiveness and efficiency of the program. This includes compliance outreach activities, IRB support, training, and maintaining content on the HSPP website. Additional HSPP
staff time and effort is also needed to increase operational efficiencies within the current human subject research compliance processes which would help alleviate some of the HSPP staff workload issues and increase the effectiveness of their performance. These operational inefficiencies relate to the need for further implementation of the new iRIS system as well as the extent of rework required by researchers and HSPP staff to generate complete applications due to errors and omissions when applications are initially submitted. The lack of sufficient resources, along with inefficient operational processes, increases the university’s risk of noncompliance with human subject research requirements which could damage the reputation of the A&M System and potentially result in sanctions from federal research agencies.

**Human Subject Research Training – Repeat Audit Observation**

Continued exceptions were noted in which required human subject research training was not completed prior to IRB approval of human subject research applications as noted in a prior audit in 2010. Five of 40 (13%) human subject research applications tested included research personnel that did not complete the required training prior to IRB approval. Management developed additional process controls to oversee completion of required training; however, these controls were not effectively implemented due to time constraints as well as difficulties in transferring researchers into the new iRIS system. Completion of required training is an important control process that helps ensure research personnel are aware of applicable federal laws and risks related to their research applications and comply with applicable laws and university procedures.

**Performance Measures – Repeat Audit Observation**

Specific performance targets to determine the effectiveness of the HSPP in achieving its goals and objectives have not been established as recommended in a prior audit in 2010. While the HSPP currently tracks performance-related information, it does not provide management with performance information that clearly communicates the HSPP’s progress in achieving its goals and objectives. In addition, the goals and objectives for the HSPP may not be clear making it difficult to determine the extent of resources and staffing needed to meet the needs of the university and researchers.
Summary of Management’s Response

Management agrees with the recommendations made in this report. Although significant changes were made to strengthen the HSPP following an extensive internal review and assessment of the program, management is taking further steps to enhance the program by adding staff to meet the growing needs of the research community; developing additional management reports; conducting a workload study; and assessing and implementing process changes to meet the needs and expectations of management and enhance service to researchers.
Detailed Results

1. Program Staffing and Efficiency

Staffing levels within the HSPP need to be reassessed to make sure that a strong human subject research compliance program is available, particularly given the importance of research growth and compliance to the university’s and A&M System’s strategic missions. The loss of any HSPP employee for an extended period could significantly impact the operation of the HSPP. HSPP staff consists of three coordinators plus an HSPP manager and post approval monitor. The three coordinators have 30% of their effort dedicated to processing and reviewing human subject research applications for the university and local A&M System research agencies. During the 11-month period from January to November 2013, more than 2,500 applications (230 applications per month) were submitted to the HSPP for review. This equates to an average of only 30 minutes per application per HSPP coordinator. The process of reviewing applications is very complicated and time consuming. Applications contain multiple requirements that are often supported with lengthy and complex research project information that HSPP staff must review, verify, and analyze prior to forwarding for IRB approval. In some cases, additional time is spent dealing with multiple instances in which applications have to be returned to researchers due to errors or omissions. The 45 Code of Federal Regulations (45 CFR), 46.103(b) (2), states that there should be sufficient staff to support the IRB’s review and recordkeeping duties.

The extent of time required to process and review applications has greatly limited the amount of time HSPP staff has devoted to other assigned duties important to maintaining the effectiveness and efficiency of the program. This includes compliance outreach activities, IRB support, training, and maintaining content on the HSPP website. Additional HSPP staff time and effort is needed to increase operational efficiencies within the current human subject research compliance processes which would help alleviate some of the HSPP staff workload issues and increase the effectiveness of their performance. For instance, although a web-based research compliance management system (iRIS) was recently implemented to automate various compliance processes, efficiencies can be improved as software conversion issues are resolved and additional management reports are generated to fully leverage this new system. In addition, the research application submission process includes delays, in that applications often require rework and must be resubmitted by research personnel, increasing the time spent by HSPP staff reprocessing and reviewing these applications which is inefficient.
The lack of sufficient resources, along with inefficient operational processes, increases the university’s risk of noncompliance with human subject research requirements which could damage the reputation of the system and potentially result in sanctions from federal research agencies. It is essential for the university and the research agencies to demonstrate a strong research compliance environment in order to attract new research opportunities and funding and to comply with applicable laws and policies.

Recommendation

Perform a workload study to determine the minimum staffing level needed within HSPP to ensure compliance with federal requirements and meet the needs of researchers and expectations of management.

Improve efficiencies within the current human subject research compliance process by developing additional management reports within the iRIS system or using other management tools.

Track application submission errors by type, researcher, and/or department to determine areas where additional guidance and enforcement efforts are needed to avoid processing delays and improve the quality of applications submitted.

Management’s Response

Management agrees with the recommendation. Management has completed an initial assessment of staffing levels and has initiated the approval process for adding one position to the human subject protection program. A workload study will be conducted and current management reports will be assessed and additional reports will be developed to meet the needs of management and enhance service to researchers. Steps will be taken to identify common application errors and provide additional guidance as appropriate.

Anticipated completion date: August 31, 2014

2. Human Subject Research Training – Repeat Audit Observation

Continued exceptions were noted in required human subject research training completion prior to IRB approval of human subject research applications as noted in a prior audit in 2010. Five of 40 (13%) applications tested did not have required human subject research training completed by all research personnel prior to IRB approval. IRB Standard Operating Procedure (SOP) 137, Training of Research Community requires that all personnel who participate in regulated human subjects'
research activities must successfully complete human subject research training to be eligible for approval as a participant on an application. Management developed this SOP as a result of our prior audit in order to provide and monitor human subject research training including sending automated training notices to research personnel and utilizing monthly reports to verify completion of training. However, these process controls were not effectively implemented due to time constraints as well as difficulties in transferring researchers into the new iRIS system. This required many researchers to be manually added to the system which was very time consuming and prone to error due to the number of active applications at the time of transition.

University Rule 15.99.01.M1, Human Subjects in Research indicates that HSPP is responsible for developing, communicating, implementing, and maintaining a Training, Outreach, and Education Plan to ensure that individuals involved with human research protection have appropriate knowledge and skills. Completion of required training is an important control process that helps ensure research personnel are aware of applicable federal laws and comply with these laws and risks related to their research applications and university procedures. Noncompliance with required training reduces the university's position for demonstrating a strong culture of research compliance.

**Recommendation**

Increase monitoring and oversight to ensure all research personnel involved with a human subjects research application have completed required training prior to IRB approval of the application as required by IRB SOP 137, Training of Research Community.

Expand the capabilities of iRIS to capture all research personnel involved with a research application. Alternatively, improve current manual processes to ensure researchers are added to the system accurately.

**Management’s Response**

*Management agrees with this recommendation. Processes will be enhanced to ensure researchers are added to the iRIS system and have completed required training prior to IRB approval.*

*Anticipated completion date: December 31, 2014*
3. Performance Measures – Repeat Audit Observation

**HSPP currently tracks performance-related information, but specific performance targets have not been established as recommended in a prior audit.** For instance, application processing times are being tracked but targets have not been established to determine whether applications are being processed in a timely manner. Absence of specific performance targets increases the risk that HSPP does not achieve its goals and objectives. In addition, expectations for HSPP may not be clear making it difficult to determine the extent of resources and staffing needed for HSPP to achieve its objectives and meet the needs of researchers. The switch to an electronic compliance management system (iRIS) and changes in leadership since the previous audit in 2010 contributed to the department’s delay in establishing formal performance targets. Targets are important as indicated in the State of Texas’ Guide to Performance Measure Management which states that achievement of performance targets will be among an institution’s highest priorities and variances from performance targets will be promptly identified and addressed. Without specific performance targets, the information collected does not provide management with information that clearly communicates if the HSPP is achieving its goals and objectives.

**Recommendation**

Develop specific measurable performance targets for the HSPP that are consistent with the program’s objectives. Track and report corresponding performance data to ensure HSPP achieves its objectives. Utilize the performance targets during the workload analysis recommended in observation #1 above to determine the resources needed for HSPP to achieve its stated performance expectations.

**Management’s Response**

*Management agrees with this recommendation. Performance targets will be developed, tracked, and utilized in connection with the workload analysis that will be conducted.*

*Anticipated completion date: August 31, 2014*
4. Integration of School of Law Research Protocols

It is unclear whether human subject research is being performed by the university’s new School of Law and whether protocols, if any, are being properly reviewed. Initial information has been gathered, but a formal plan has not yet been developed to identify and integrate research protocols at the new Texas A&M School of Law into the university’s human subject research compliance process. As a result, there is a greater potential for noncompliance with human subject research requirements. A&M System Regulation 15.99.01, Use of Human Subjects in Research, requires all research on human subjects, whether funded or unfunded, be approved by the member’s IRB before the initiation of the research project.

Recommendation

Determine the extent to which human subject research is occurring at the Texas A&M School of Law. Complete the integration of any human subject research compliance processes for the Texas A&M School of Law to the university’s processes.

Management’s Response

Management agrees with this recommendation and expects to complete its plan for integration by August 31, 2014.

Anticipated completion date: August 31, 2014

5. Conflict of Interest Disclosure Statement

Seven of 40 (18%) human subject research applications tested involved research personnel that did not fully or properly complete a conflict of interest statement as required. Disclosure statements were often submitted, but not completed fully or properly by research personnel. Monitoring of this requirement by HSPP was limited due partly to staffing issues as well as a limitation within the iRIS system that does not recognize all research personnel by position title. In addition, the current conflict of interest disclosure form may be confusing and does not have certain edit checks to control the information being provided.

A&M System Regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research, and 45 CFR Part 94 indicate that disclosing financial conflicts of interest to human subject research participants is a method to manage, reduce, or eliminate these conflicts. IRB SOP 105, Investigator Conflict of Interest, states it is imperative
that investigators with conflicts of interest declare those conflicts for review by the IRB to ensure adequate protection of human research subjects. Lack of proper conflict of interest disclosures increases the risk of noncompliance with human subject research requirements.

**Recommendation**

Provide additional guidance and oversight to ensure all research personnel involved with human subject research properly and fully complete and submit the required conflict of interest disclosure statement prior to IRB approval of the respective research application. Redesign the current conflict of interest disclosure form as needed to ensure it is clear and understandable and includes automated edit checks within the form where feasible.

Determine whether researcher conflicts of interest disclosures are addressed in other areas of the university’s research compliance process to avoid potential duplication of effort in this area.

**Management’s Response**

*Management agrees with this recommendation and is assessing its disclosure process to develop and implement changes to reduce the risk of noncompliance and avoid duplication of effort in other areas.*

*Management expects to complete its assessment and develop an updated disclosure process by December 31, 2014.*

6. **Disaster Recovery Planning**

The current disaster recovery plan for the iRIS system does not address all necessary elements needed to ensure this critical system remains available for research compliance operations in the event of a disaster. Critical research data is being backed up and tested; however, other disaster recovery planning elements required by Texas Administrative Code (TAC) 202.24, *Business Continuity Planning* have not yet been fully included in the plan. These elements include measures of the impact and magnitude of loss or harm that will result from an interruption; recovery resources and a source for each; step-by-step implementation instructions; and provisions for annual testing. Loss of availability of the iRIS system could impact human subject research compliance operations especially given the increasing use of the system for protocol submission and tracking. iRIS was only recently implemented and management indicated that they plan to utilize a new university
template which contains all the required elements for a disaster recovery plan when updating their iRIS disaster recovery plan.

**Recommendation**

Complete current plans to update the existing disaster recovery plan for the iRIS system to address all necessary elements required by TAC 202.24, Business Continuity Planning. Include the updated plan in the business continuity plan for the Division of Research Systems Group as required.

**Management’s Response**

*Management agrees with this recommendation and has updated the existing disaster recovery plan for the iRIS system to address all necessary elements required by TAC 202.24, Business Continuity Planning. The updated plan has been included in the business continuity plan for the Division of Research Systems Group.*
Basis of Review

Objective and Scope

The overall objective of this audit was to review controls and processes at Texas A&M University to ensure human subject research activities are in compliance with laws and policies. The selected human subject research compliance areas reviewed included research applications, training, IRB membership, investigations of noncompliance, and information technology controls. The audit focused primarily on compliance and monitoring processes in these areas. In addition, a follow-up audit was performed of our prior report, Review of the Human Subjects Protection Program, which was issued in the Third Quarter Report, Fiscal Year 2010. The objective of this follow-up audit was to determine if recommendations in our prior audit were implemented. The audit period focused primarily on activities from September 1, 2012 to October 31, 2013. Fieldwork was conducted from October to November, 2013.

Criteria

Our audit was based upon standards as set forth in the System Policy and Regulation Manual of the Texas A&M University System; Texas A&M University Rules and Standard Administrative Practices; IRB Standard Operating Procedures, Title 45 Code of Federal Regulations (CFR) Part 46 Protection of Human Subjects; Texas Administrative Code 202.74 Business Continuity Planning; the State of Texas’ Guide to Performance Measure Management; and other sound administrative practices. This audit was conducted in conformance 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.
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