

**Office of Compliance and Consultation
Work Plan for High-Risk Areas
FY 2007**

High-Risk Area

Scope

First Quarter FY 2007

September 2006

- Information Security (HIPAA, GLB, SSN, TAC)
 - Meet with CIO and Security Officer to determine their monitoring plan for fiscal year 2007. Also, determine if the risk assessment is current and updated for SSN and HIPAA security.
- Clinical Research
 - Meet with Assistant Vice President for Research Operations to determine if timeline for implementing training and the infrastructure for Clinical Research Office has been updated.
- Business Continuity Planning/Preparedness
 - Meet with CBO to determine if a timeline has been implemented for developing a "Business Continuity Plan".
- Contracting
 - Meet with CBO to determine the status of programming software for the management of contracts.
- Human Subjects
 - Meet with Director of the IRB to review the status of formalizing new policies and procedures, including HIPAA, and developing training for research staff. The Office of Compliance & Consultation will complete the review of two studies.
- FMLA/Leave Administration
 - Meet with AVP for Human Resources to determine if a formal training session and monitoring plan have been developed.
- Graduate Medical Education
 - Meet with Associate Dean of GME and determine the monitoring conducted as a result of the last resident survey, and the actions taken on non-compliant departments.
- Records Management
 - Meet with the Records Management Officer and determine the departments reviewed. Review the results of the completed departments. Also, validate the number trained for the annual report.
- Select Agents
 - Meet with the AVP for Risk Management and Safety to determine the status of implementing the CDC recommendations.
- Conflict of Interest
 - Conduct a review by comparing the minutes of the Committee meetings to the list of management plans. Determine the status of the management plans.

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October 2006

- Conflict of Interest Attend the monthly Conflict of Interest Committee meeting.
- Human Subjects Meet with Director of IRB to review the status of finalizing policies and procedures. The Office of Compliance & Consultation will complete three reviews of studies.
- Select Agents Conduct a review to determine if the outstanding CDC recommendations were properly implemented.
- Fire Marshal Recommendations Meet with AVP for Risk Management and Safety to review the status of implementing the Fire Marshal recommendations.

November 2006

- Human Subjects Meet with Director of IRB to review status of finalizing policies and procedures. The Office of Compliance & Consultation will complete three reviews of studies.
- Conflict of Interest Attend the monthly Conflict of Interest Committee meeting.

Second Quarter FY 2007

December 2006

- Clinical Research Meet with Assistant Vice President for Research Operations to determine the status of training and if the infrastructure for the clinical trials monitoring process has been developed.
- Information Security (HIPAA, GLB, SSN, TAC) Meet with CIO and Security Officer to review their monitoring plan. Also, review the plan for addressing risks in the decentralized environment.
- Annual Report on SSN Complete annual report to the Chancellor on Social Security Numbers (SSNs).
- Human Subjects Meet with Director of IRB to review status of finalizing policies and procedures for accreditation. The Office of Compliance & Consultation will complete three reviews of studies.
- Graduate Medical Education Meet with Associate Dean for GME to review status of compliance with the 80-hour rule.

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Business Continuity Planning/Preparedness	<ul style="list-style-type: none"> Meet with CBO to review the timeline for development of the "Business Continuity Plan".
Contracting	<ul style="list-style-type: none"> Meet with CBO to determine the status of scanning and accounting for contracts.
FMLA/Leave Administration	<ul style="list-style-type: none"> Meet with AVP for Human Resources to determine if training has been completed, and if the formal monitoring plan was implemented.
Records Management	<ul style="list-style-type: none"> Meet with Records Management Officer and determine the departments reviewed. Review the results of the completed departments. Also, validate training numbers report for last quarter.
Conflict of Interest	<ul style="list-style-type: none"> Attend the monthly Conflict of Interest Committee meeting.
January 2007	
Human Subjects	<ul style="list-style-type: none"> Meet with Director of IRB to review any compliance issues or concerns. The Office of Compliance & Consultation will complete three reviews of studies.
Fire Marshal Recommendations	<ul style="list-style-type: none"> Meet with AVP for Risk Management and Safety to review the status of implementing the Fire Marshal recommendations.
Conflict of Interest	<ul style="list-style-type: none"> Attend the monthly Conflict of Interest Committee meeting.
Select Agents	<ul style="list-style-type: none"> Review a sample of laboratory inspections completed by Environmental Health & Safety, and evaluate the process and findings noted.
February 2007	
Human Subjects	<ul style="list-style-type: none"> Meet with Director of IRB to review any compliance issues or concerns. The Office of Compliance & Consultation will complete three reviews of studies.
Conflict of Interest	<ul style="list-style-type: none"> Conduct a follow-up review on the management plans.

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Third Quarter FY 2007

March 2007

- **Clinical Research** Meet with Assistant Vice President for Research Operations to review the monitoring of training and the monitoring plan for clinical trials.
- **Information Security (HIPAA, GLB, SSN, TAC)** Meet with CIO and Security Officer to review their monitoring activities.
- **Human Subjects** Meet with Director of IRB to review any compliance issues or concerns. The Office of Compliance & Consultation will complete three reviews of studies.
- **Graduate Medical Education** Meet with Associate Dean for GME to review status of compliance with the 80-hour rule.
- **Business Continuity Planning/Preparedness** Meet with CBO to review the status and documentation for implementing the "Business Continuity Plan".
- **Contracting** Conduct a compliance review of the system to account for contracts.
- **FMLA/Leave Administration** Meet with AVP for Human Resources to review their monitoring plan.
- **Records Management** Conduct a review of the records management process and training program to determine if the area is ready for an audit review.
- **Conflict of Interest** Attend the monthly Conflict of Interest Committee meeting.

April 2007

- **Human Subjects** Meet with Director of IRB to review an compliance concerns or issues. The Office of Compliance & Consultation will complete three reviews of studies.
- **Conflict of Interest** Attend the monthly Conflict of Interest Committee meeting.
- **Research - Time & Effort Reporting** Review the monitoring process for time and effort reporting completed by the Office of Sponsored Programs. Determine if the results reported to the VP for Research and Compliance Officer were accurate.

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Fire Marshal Recommendations	<ul style="list-style-type: none"> Meet with AVP for Risk Management and Safety to review the status of implementing the Fire Marshal recommendations.
Select Agents	<ul style="list-style-type: none"> Meet with the AVP for Risk Management and Safety to review any monitoring activities over select agents.
May 2007	
Human Subjects	<ul style="list-style-type: none"> Meet with Director of IRB to review any compliance concerns or issues. The Office of Compliance & Consultation will complete three reviews of studies.
Conflict of Interest	<ul style="list-style-type: none"> Attend the monthly Conflict of Interest Committee meeting.
Fourth Quarter FY 2007	
June 2007	
Clinical Research	<ul style="list-style-type: none"> Meet with AVP for Research Operations to review their monitoring for clinical trials.
Information Security (HIPAA, GLB, SSN, TAC)	<ul style="list-style-type: none"> Meet with CIO and Security Officer to review their monitoring activities.
Human Subjects	<ul style="list-style-type: none"> Meet with Director of IRB to review any compliance concerns or issues.
Graduate Medical Education	<ul style="list-style-type: none"> Meet with Associate Dean for GME to review the results of the resident's survey on the 80-hour rule.
Business Continuity Planning/Preparedness	<ul style="list-style-type: none"> Meet with CBO to determine the status of finalizing the "Business Continuity Plan".
Contracting	<ul style="list-style-type: none"> Review the status of this area to determine if the risk can be removed from the high-risk list.
FMLA/Leave Administration	<ul style="list-style-type: none"> Meet with AVP for Human Resources to review formal monitoring for the quarter.
Records Management	<ul style="list-style-type: none"> Follow-up on any issues from the compliance review and determine the status for audit.
Conflict of Interest	<ul style="list-style-type: none"> Attend the monthly Conflict of Interest Committee meeting.

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<p>Risk Assessment</p> <p style="text-align: center;">July 2007</p> <p>Human Subjects</p> <p>Conflict of Interest</p> <p>Risk Assessment</p> <p>Fire Marshal Recommendations</p> <p>Select Agents</p>	<ul style="list-style-type: none"> • Distribute documents for the FY 2008 risk assessment. • Meet with Director of IRB to review any compliance issues or concerns. The Office of Compliance & Consultation will complete three reviews of studies. • Attend the monthly Conflict of Interest Committee meeting. • Meet with management to finalize risks for FY 2008. • Meet with AVP for Risk Management and Safety to review the status of implementing the Fire Marshal recommendations. • Meet with the AVP for Risk Management and Safety to review any monitoring activities over select agents.
<p style="text-align: center;">August 2007</p> <p>Human Subjects</p> <p>Conflict of Interest</p> <p>Risk Assessment</p> <p>Annual Report</p>	<ul style="list-style-type: none"> • Meet with Director of IRB to review any compliance issues or concerns. The Office of Compliance & Consultation will complete three reviews of studies. • Attend the monthly Conflict of Interest Committee meeting. • Have Audit & Compliance Committee approve risk assessment and send to UT System. • Prepare annual report for UT System on FY 2007 activity.