

AUDITOR'S REPORT

HARRIS HEALTH SYSTEM RESEARCH CONTROLS



October 30, 2014

**Barbara J. Schott, C.P.A.
Harris County Auditor**

Mike Post, C.P.A.
Chief Assistant County Auditor
Accounting Division

Mark Ledman, CISA, M.P.A.
Chief Assistant County Auditor
Audit Division



1001 Preston, Suite 800
Houston, Texas 77002-1817
(713) 755-6505

FAX (713) 755-8932
Help Line (713) 755-HELP

BARBARA J. SCHOTT, C.P.A.
HARRIS COUNTY AUDITOR

October 30, 2014

Mr. George Masi
President and Chief Executive Officer
Harris Health System
2525 Holly Hall
Houston, Texas 77054

RE: Grants and Research Controls for the six months ended August 31, 2013

The Audit Services Department performed procedures relative to Harris Health System (Harris Health) Grant and Research Controls. The objective of the engagement was to selectively evaluate critical controls for grant and research projects. The following procedures were performed:

- Reviewed policies for grants and research.
- Selectively met with employees responsible for grant and research projects to obtain an understanding of administrative and financial controls.
- Reviewed reports on independent oversight and testing procedures performed for state and federal grants.
- Reviewed and evaluated controls for approving grant and research projects.
- Selectively tested controls over grant payments and compliance with grant contracts.
- Reviewed and evaluated controls for compensation received for research conducted in facilities and services provided to research patients.
- Reviewed and evaluated reporting for grants and research.

At the request of Harris Health Management, the results for the procedures related to research included in this scope letter are reported in this separate Auditor's Report to allow presentation to the Harris Health System Board of Managers' Joint Conference Committee. Grants related results, issues, and recommendations are reported in a separate Auditor's Report.

The engagement process included providing former President and Chief Executive Officer David Lopez with engagement and scope letters and conducting an entrance and exit conference with your personnel. The purpose of the letters and conferences were to explain the process, identify areas of concern, describe the procedures to be performed, discuss issues identified during the engagement, and solicit suggestions for resolving the issues. A draft report was provided to you and your personnel for review.

Mr. George Masi
President and Chief Executive Officer

The enclosed Auditor's Report presents the significant research related issues identified during our procedures, recommendations developed in conjunction with your staff, and any actions you have taken to implement the recommendations. Less significant research related issues and recommendations have been verbally communicated to your staff.

We appreciate the time and attention provided by you and your staff during this engagement.

Sincerely,

A handwritten signature in blue ink, reading "Barbara J. Schott", with a long horizontal flourish extending to the right.

Barbara J. Schott
County Auditor

cc: Harris Health System Board of Managers
District Judges
County Judge Ed Emmett
Commissioners:
 R. Jack Cagle
 El Franco Lee
 Jack Morman
 Steve Radack
Devon Anderson
Vince Ryan
William J. Jackson

TABLE OF CONTENTS

OVERVIEW	5
RESULTS	7
ISSUES AND RECOMMENDATIONS	8
Approving Research Studies	8
Reimbursing Indirect Costs.....	9
Identifying Indirect Cost Payments.....	9
Reimbursing Indirect Costs Timely.....	10
Remitting Payments to Cash Management.....	10
Billing for Research Services.....	11
Separating Invoicing and Recording Duties	13
Collecting Institution Accounts Receivable	13
Reporting Research Status and Results	15
Designating Research Approvers.....	16
RISK ASSESSMENT AND SUMMARY OF RECOMMENDATIONS.....	18

OVERVIEW

Harris Health supports the acquisition of new knowledge to improve patient care by allowing institutions that perform research (research institutions) to access Harris Health facilities, staff, patients, or information. According to Harris Health records, 509 research studies were allowed access to Harris Health during the eight months ended August 31, 2013. The 509 research studies were primarily performed by the following research institutions: Baylor College of Medicine (Baylor), The University of Texas Health Science Center at Houston (UTHealth), or UT MD Anderson Cancer Center (MDACC).

The research institutions may fund their own research, or may enter into formal written agreements to receive funding from public or private research sponsors. The agreements describe the studies and how the sponsors will pay the research institutions. After the research institutions enter into the agreements, they apply to Harris Health to access facilities, staff, patients, or information.

Applications to access Harris Health are submitted to the Harris Health Office of Research & Sponsored Programs (Research Office). Prior to submitting an application, research which involves obtaining data through intervention or interaction with human subjects, or that identifies private information must have the approval of a recognized University or Organization Institutional Review Board (IRB) as defined in the Harris Health's Federal Wide Assurance agreement.

Applications received by the Research Office are forwarded to be approved by the respective chief of staff and administrator at the Harris Health hospital or health center where the research study will be conducted. Harris Health policy also requires that access to Harris Health facilities, staff, patients, or information by research studies be approved by the Harris Health President and Chief Executive Officer (or designee).

The level of access provided to Harris Health facilities, staff, patients, or information depends on the research study type. Clinical trials may require dispensing of pharmaceuticals and/or providing patient clinical services. Retrospective record reviews may only require access to information systems data.

The Research Office prepares a financial agreement for research studies proposing to access Harris Health facilities, staff, patients, or information. The financial agreements document how Harris Health will be paid for services provided to support the study. Financial agreements are approved by the Research Office, and by either the researchers (Principal Investigators) or representatives of the financial/business office at the institutions performing the research.

Executed financial agreements are maintained by the Research Office. A general line item for indirect costs is included on the financial agreements of studies funded by public or private research sponsors. Harris Health does not create an invoice (bill) for indirect cost. The research institution is responsible for accurately paying Harris Health for indirect cost reimbursement due.

Harris Health invoices the Principal Investigators monthly for services provided by Harris Health to support research studies. A Patient Account Representative in Patient Financial Services prepares the invoices and submits them to be reviewed and approved by a manager in Patient Financial Services before they are sent to the Principal Investigators. The invoices instruct the research institutions to send payments directly to the Cash Management Department for deposit in Harris Health's bank account.

RESULTS

Based on procedures performed, Harris Health has developed and is following policies and procedures for review and approval of research studies before they are allowed to access Harris Health facilities, staff, patients, or information. The policies and procedures are designed to protect human subjects and to provide reimbursement to Harris Health for costs incurred supporting research studies.

Although the policies and procedures have been developed and are being followed, additional critical controls are needed to improve Harris Health coordination with the research institutions to ensure:

- All research studies that access Harris Health facilities, staff, patients, or information are approved by Harris Health management.
- Reports on active and terminated research studies are timely provided to Harris Health.
- Appropriate communication occurs when Harris Health provides services so that the invoices to the research studies will be accurate and complete.

In addition, improvements are needed to Harris Health controls for:

- Ensuring duties are adequately separated for employees preparing invoices and maintaining invoice and payment records.
- Collecting unpaid invoices for services provided to research institutions.
- Monitoring the receipt of Harris Health indirect cost reimbursement.

These and other issues are discussed in more detail in the Issues and Recommendations matrix below.

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
Approving Research Studies	Per Policy 3.05, Research, research studies that access Harris Health facilities, staff, patients, or information must be approved by the chief of staff and administrator at the Harris Health hospital or health center where the research study will be conducted.	<p>Lists of research studies that access Harris Health were obtained from the research institutions and compared to Research Office records and several research studies were identified that were not approved by Harris Health.</p> <p>Not submitting all research studies for approval does not comply with Policy and increases the risk of unidentified patient privacy risks, or lost reimbursement from the research institutions.</p>	<p>Research Office Management should inform appropriate personnel at the research institutions of the unapproved research studies identified, and request the research institutions to submit the research studies for approval. In addition, the Research Office should request lists of research studies that access Harris Health to compare to the Research Office records and appropriate action should be taken if unapproved studies are identified. The results of the comparisons should be reported to the research institutions, the Harris Health Corporate Compliance Office, and other Harris Health appropriate executive management.</p>	<p>Research Office Response: Agree with issue and recommendation.</p> <p>1. Research Office will work with research institutions to obtain quarterly reports of approved research studies and compare to Research Office records and take action as noted in audit recommendation. Anticipated date of completion of implementation of process to address issues is September 1, 2014.</p>

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
Reimbursing Indirect Costs	Harris Health received \$373,138 in indirect cost reimbursement payments from research institutions during the six months ended August 31, 2013. The financial agreements prepared by the Research Office include the rate (percentage of direct cost) at which indirect cost reimbursement amounts will be paid, but not the amount because payments are dependent on actual direct cost.	Research studies with a general line on the financial agreements for indirect cost reimbursement are not monitored to determine if payments are received. Not monitoring whether indirect cost reimbursement payments are received increases the risk that unpaid indirect cost reimbursements due to Harris Health may not be identified and collected.	Research Office Management, in conjunction with Patient Financial Services Management, should monitor to determine whether indirect cost reimbursement payments are received for research studies with an indirect cost reimbursement general line item on the financial agreements. If payments are not received, Research Office Management should contact and request that the Principal Investigators or representatives of the financial/business office confirm no indirect cost reimbursement payments are due Harris Health.	Research Office Response: Agree with issue and recommendation. Research Office management will work with Patient Financial Services to monitor and determine indirect cost reimbursement for research studies. If payments are not received, Research Office Management will contact and request that the Principal Investigators or representatives of the financial/business office confirm no indirect cost reimbursement payments are due Harris Health. Anticipated date of completion of implementation of process to address issues is September 1, 2014.
Identifying Indirect Cost Payments	Each research study is assigned a unique IRB Protocol number.	Indirect cost reimbursement payments from Baylor did not include the related research studies IRB Protocol numbers. As a result, the Research Office	Research Office Management should request that Baylor include IRB Protocol numbers for the research studies for which indirect cost	Research Office Response: Agree with the issue and recommendation. Anticipated date of completion of implementation of process to

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Identifying Indirect Cost Payments		cannot reconcile payments to research study financial agreements, which could result in unpaid indirect cost reimbursement not being detected, causing lost reimbursement.	reimbursement payments are remitted.	address issues is September 1, 2014.
Reimbursing Indirect Costs Timely		All research institutions do not timely remit indirect cost reimbursement to Harris Health. UTHealth paid indirect costs reimbursement earned during the year ended February 28, 2013, in a lump sum payment of \$222,158 in August 2013. Not requiring timely payment decreases Harris Health's cash on hand balance.	Research Office Management should request that UTHealth remit indirect cost reimbursement payments to Harris Health timely.	Research Office Response: Agree with issue and recommendation. Research Office Management will request that UTHealth remit indirect cost reimbursement payments to Harris Health timely. Anticipated date of completion of implementation of process to address issues is September 1, 2014.
Remitting Payments to Cash Management		The payment for UTHealth referenced in the previous issue (Reimbursing Indirect Costs Timely) was not sent directly to the Cash Management Department, which increases risk of loss or misappropriation of	Research Office Management should ensure UTHealth is instructed to remit payments for indirect cost reimbursement directly to the Cash Management Department.	Research Office Response: Agree with issue and recommendation. Research Office Management will notify UTHealth to send payments directly to Harris Health Cash Management Department. Anticipated

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Remitting Payments to Cash Management		funds.		date of completion of implementation of process to address the issues is September 1, 2014.
Billing for Research Services	During the six months ended August 31, 2013, Harris Health invoiced \$57,828 for research related services. The invoices sent contained a written statement that research institutions are required to submit registration and patient study information (patient name, medical record number, research activities with dates of services) to the Harris Health billing office.	A standard process is not followed to obtain registration and patient study information to use for invoicing research institutions for the services provided by Harris Health. As a result, there is an increased risk of inaccurate or incomplete billings, which could result in lost revenue.	Patient Financial Services Management should require the Principal Investigators (or their staff) to report registration and patient study information to the Harris Health billing office monthly using standard reporting forms. In addition, procedures should be developed for communication and training of appropriate personnel at the research institution when new studies begin.	Patient Financial Services Response: Agree with recommendation. There are two phases that will be required to as it relates to this recommendation. As an interim solution and for the first phase of this project (one that will be completed by 12/31/14), Patient Financial Services will work with Research Office Management and Accounting to make sure the Principal Investigators (or their staff) have access to the study's hospital account record in order for the transfer of charges from the primary account to the research to be completely transparent. Patient Financial Services will also make sure Research Office

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Billing for Research Services				Management receives a monthly copy of the manual spreadsheet that summarizes the patients and their research services in order to assist the Research Office Management with their monthly reconciliation processes. As a second phase, one to be completed by the end of the fiscal year 2016, Patient Financial Services will work with the Information Technology team to implement EPIC's (the billing system's) Research module and will start by getting the Information Technology team to create a project plan that will be prioritized against all of the projects in the queue. (The prioritization meeting was scheduled 8/26/14 whereby we will work toward a plan geared to having the module implemented.)

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
Separating Invoicing and Recording Duties	A Patient Accounts Representative prepares monthly invoices to research studies for services provided by Harris Health. The same Patient Accounts Representative records the invoices and payments on the books of record which are maintained on electronic spreadsheets.	The duties of preparing invoices and of recording invoices and payments on electronic spreadsheets are not inadequately separated. As a result, there is an increased risk of misappropriation of funds.	Patient Financial Services Management should assign responsibilities for preparing, and for recording invoices and payments to separate employees.	Patient Financial Services Response: Agree with recommendation. Patient Financial Services will work with Research Office Management, the schools, and Accounting to make sure checks are received into and posted to the individual research hospital account record by a cash poster rather than the biller/follow-up representatives. Because this update will require a change in the way the schools send invoices (meaning we will need payment information that summarizes each payment down to the patient level and in a manner consistent with every other payer), we will work with the schools to have this part of the project completed by 3/1/15 .
Collecting Institution Accounts Receivable		An aging of accounts receivable from research institutions is not prepared and collection activities do	Patient Financial Services Management should prepare a monthly aging of research institutions	Patient Financial Services Response: Agree with recommendation. There are two phases that will be

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Collecting Institution Accounts Receivable		not occur after the invoices are sent. As a result, a several invoices going back for several months were unpaid as of August 31, 2013. Without adequate collection activities, there is an increased risk of lost revenue.	accounts receivable. The aging should be provided to Research Office Management for review. Research Office Management, in conjunction with Patient Financial Services Management, should establish and implement collection activities for research institution invoices not paid timely, including guidelines for actions to be taken on delinquent accounts.	required to as it relates to this recommendation. As an interim solution and for the first phase of this project (one that will be completed by 3/1/15), Patient Financial Services will create a process whereby the biller/follow-up representative will: <ol style="list-style-type: none"> 1) invoice the institution using a standardized invoice number (preferably the hospital account record), 2) created a process whereby the invoices are mailed to the schools monthly for 90 days with escalating dunning messages, 3) have delinquent flags applied to the study-based hospital account record's notifying patient financial service's staff that the payments for services >90 days old have not been paid, 4) work with the institution's leadership on a plan of action for studies that are not paid within 90 days.

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Collecting Institution Accounts Receivable				As a second phase, one to be completed by the end of the fiscal year 2016, Patient Financial Services will work with the Information Technology team to implement EPIC's (the billing system's) Research module and will start by getting the Information Technology team to create a project plan that will be prioritized against all of the projects in the queue. (The prioritization meeting was scheduled 8/26/14 whereby we will work toward a plan geared to having the module implemented.)
Reporting Research Status and Results	Policy 3.05 requires Principle Investigators to provide the Research Office annual status reports for active research studies. In addition, abstracts of findings and statistics on Harris Health patients enrolled are required for research studies completed	Status and completion/termination reports are not consistently provided to the Research Office by Principal Investigators for all research studies. As a result, policy is not being followed and the Research Office is not receiving needed information for	Research Office Management should ensure that appropriate personnel at the research institutions are informed of the reporting requirements. In addition, Research Office Management should develop a process for informing appropriate	Research Office Response: Agree with issue. Current processes in place to meet recommendation include. 1. Research institutions are informed of Harris Health reporting requirements. A summary of research results and publications

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Reporting Research Status and Results	or terminated.	reporting on research studies that access Harris Health.	personnel at the research institution of delinquent reports and for escalating communications to senior management if necessary.	is also requested on the Continuing Review (renewal) and Final Report forms. 2. The Research Report, where research results are presented to the Joint Conference Committee, is first submitted to Chiefs of Staff from each Harris Health pavilion to enlist their assistance in gathering research results prior to submission to Joint Conference Committee.
Designating Research Approvers	Harris Health Policy 3.05 states that research studies that accesses Harris Health facilities, staff, patients, or information must be approved by the Harris Health President and Chief Executive Officer (or designee) prior to data collection or subject recruitment.	There is no formal documentation of designees authorized to approve research studies for the President and Chief Executive Officer. As a result, there is a risk that research studies that do not have the documented approval of the President and Chief Executive Officer were not approved in accordance with policy.	Research Office Management should obtain a letter from the President and Chief Executive Officer designating Harris Health personnel who are authorized to approve research studies that access Harris Health.	Research Office Response: Agree with the issue and recommendation. Research Office Management has obtained a letter from the President and Chief Executive Officer designating Harris Health personnel who are authorized to approve research studies that access Harris Health. Completion of

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Designating Research Approvers				implementation of process to address issues was completed on July 18, 2014.

RISK ASSESSMENT AND SUMMARY OF RECOMMENDATIONS

The risk matrix below presents the assessed level of risk or exposure identified during our procedures. Inherent risk relates to factors that because of their nature cannot be controlled or mitigated by management. Inherent risk includes factors such as legislative changes, number and dollar amount of transactions processed and/or complex nature of transactions. Control risks relate to factors that can be influenced or controlled by management. Controls such as policies and procedures, electronic or manual approvals, system security access, and separation of job responsibilities may be instituted by management in order to mitigate control risk. Control risk is assessed during the planning phase in order to establish the nature, timing, and extent of testing and at the conclusion of the engagement in order to incorporate actions taken to implement our recommendations. The overall risk considers a combination of inherent and control risks.

Inherent Risk:	Control Risk:		Overall Risk:
<input checked="" type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low	Prior to Procedures	After Procedures	<input checked="" type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low
	Needed Improvement	Needs Improvement	
Type of Procedures: Audit			
Purpose: To selectively evaluate critical controls for research projects.			
Outstanding Audit Recommendations:			
Priority Rating:	Audit Recommendations: Research Controls		
1	Inform personnel at the research institutions of the unapproved research studies identified, and request the research institutions to submit the research studies for approval. Monthly request information from research institutions to compare to the Research Office records and appropriate action should be taken if unapproved studies are identified. The results of the comparisons should be reported to the research institutions, to the Harris Health Corporate Compliance Office, and other appropriate executive management.		
1	Monitor to determine whether indirect cost reimbursement payments are received for research studies with an indirect cost reimbursement general line item on the financial agreements. If expected payments are not received, contact research institutions and request confirmation that no indirect cost reimbursement payments are due Harris Health.		
1	Request that the research institutions include IRB Protocol numbers for the research studies for which indirect cost reimbursement payments are remitted.		
1	Monitor research studies with a general line for indirect cost reimbursement on the financial agreements and follow-up with research institutions to ensure that indirect cost reimbursement payments are remitted to Harris Health timely.		

1	Include language on the financial agreements that instructs the research institutions that payments for indirect cost reimbursement should be remitted directly to the Cash Management Department.
1	Require the Principal Investigators (or their staff) to report registration and patient study information to the Harris Health billing office monthly using standard reporting forms. In addition, develop procedures for communication and training of appropriate personnel at the research institution when new studies begin.
1	Assign responsibilities for preparing, and for recording invoices and payments to separate employees.
1	Prepare a monthly aging of research institutions accounts receivable, and establish and implement collection activities for research institutions invoices not paid timely, including guidelines for actions to be taken on delinquent accounts.
1	Ensure that appropriate personnel at the research institutions are informed of research study reporting requirements. In addition, develop a process for informing appropriate personnel at the research institution of delinquent reports and escalating communications to senior management if necessary.
1	Obtain a letter from the President and Chief Executive Officer designating Harris Health personnel who are authorized to approve research studies that access Harris Health.
Priority Rating	<ol style="list-style-type: none"> 1. Implement immediately (30 – 90 days) – Serious internal control deficiencies; or recommendations to reduce costs, maximize revenues, or improve internal controls that can be easily implemented. 2. Work towards implementing (6 – 18 months) – Less serious internal control deficiencies, or recommendations that can not be implemented immediately because of constraints imposed on the department (i.e., budgetary, technological constraints, etc.). 3. Implement in the future (two – three years) – Recommendations that should be implemented, but that can not be implemented until significant and/or uncontrolled events occur (i.e., legislative changes, buy and install major systems, requires third party cooperation, etc.).