

October 4, 2011

ELIZABETH BARRETT-CONNOR, M.D.
Principal Investigator
0607

JANE MILNER-MARES
Business Officer
0631-C

***Subject: Research Subject Payments – Research Unit Scrip Management
AMAS Audit Project 2011-34E***

Audit & Management Advisory Services (AMAS) has completed a review of research scrip management processes for five research units as part of the Fiscal Year 2010-11 audit plan. This report summarizes the results of the review of scrip usage within the Family and Preventive Medicine (FPM) department. As part of our review, we examined the use of scrip for a specific project, titled *Post Diabetes Prevention Program Outcome Study* (Study), which was managed by Principal Investigator Elizabeth Barrett-Connor, M.D.

Background

UCSD research investigators (PIs) conduct clinical research projects that require the participation of human subjects. To encourage subject participation, PIs may include subject compensation in their Institutional Review Board (IRB) approved research plans. In the past, research related payments were issued using cash, checks, or food/merchandise vouchers. Check payments were not an optimal solution because in most cases, checks could not be issued to subjects at the time of the visit. In addition, most research units found it difficult to keep cash on hand. Scrip (a convenient cash equivalent similar to a money order and redeemable at a bank) was identified as a good alternative to other payment methods because it satisfied the business requirement for flexibility, improved control, and subject confidentiality. Some advantages of issuing scrip include:

- Scrip orders can be processed in a short time period;
- Research subjects can be paid at each visit;
- Scrip can be issued in a standard pre-numbered format;
- Scrip can be ordered in specified denominations; and
- Scrip can be tracked, audited, and secured.

The Scrip Program is administered campus-wide by the UCSD Business and Financial Services Department (BFS) Disbursements Division (Disbursements). After scrip orders are processed, the responsibility for managing scrip passes to Scrip Coordinators in departments or research units. For the FPM study selected for review, scrip responsibilities were shared by a Study Coordinator, three other staff members. The Fund Manager is minimally involved in scrip processing.

***Research Subject Payments – Scrip Management
Audit & Management Advisory Services Project 2011-34E***

Because scrip is considered a cash equivalent, University of California (UC) Business and Finance Bulletin 49, *Policy for Cash and Cash Equivalents Received* (BUS 49) requirements apply.

The results of our evaluation of campus Scrip Program management controls in general were reported to the Director of Disbursements in the final report for AMAS Project #2011-34. This report concluded that overall Scrip Program business process controls were working effectively, and met BUS 49 cash management requirements. Specifically, Disbursements' management had implemented adequate separation of duties, obtained appropriate authorization and approvals, and had ensured that scrip was properly secured and periodically reconciled.

Audit Objective, Scope and Procedures

The objective of our review was to verify that required procedures had been implemented in the clinical research environment to ensure that:

- Scrip was issued to research subjects in accordance with an IRB-approved research plan;
- Scrip management processes complied with BUS 49 cash management requirements; and,
- All scrip payments were accounted for.

We performed the following procedures to achieve the project objective:

- Reviewed applicable UC and UCSD policies including: UC Disbursements D-371-12-1, *Accounting for and Tax Reporting of Payments Made Through the Vendor System*; BUS 49; guidelines posted on the Human Research Protections Program website; procedures posted on the Disbursements webpage on Blink; BFS Scrip Overview Procedures; and BFS Scrip Issuance Procedures;
- Interviewed the FPM research unit Fund Manager;
- Analyzed FPM research unit processes for ordering, issuing, returning, reconciling, storing and recording scrip; and,
- Performed a count of scrip on hand, and reviewed documentation supporting the issuance of scrip for the FPM sample Study.

Conclusion and Supporting Comments

Based on our review procedures, we concluded that in FPM, scrip was issued to research subjects in accordance with an IRB-approved research plan and all scrip was accounted for. However, we noted opportunities for improvement in scrip management processes and supporting documentation to improve compliance with BUS 49 cash management requirements.

We noted that the Scrip Order Forms included all required information. Procedures had been implemented in the clinical research environment to ensure that scrip was issued to research

***Research Subject Payments – Scrip Management
Audit & Management Advisory Services Project 2011-34E***

subjects in accordance with the IRB-approved research plan. To comply with Internal Revenue Service (IRS) regulations, research unit Scrip Coordinators are instructed to provide Disbursements with the information required to prepare tax documents for all participants who receive more than \$600 in a given year. We noted that that Study controls prevented participants from accumulating more than \$600 in scrip payments per year.

Staff responsibilities for receiving, issuing and reconciling scrip inventory were documented and adequately separated. Scrip issue logs were completed and copies of receipts issued to patients were retained. The quarterly summary of scrip transactions was submitted to Disbursements.

Opportunities for process improvements are discussed in more detail in the remainder of this report.

Observations and Management Corrective Actions

A. Scrip Accountability

The department did not have adequate procedures to ensure individual accountability for scrip.

BUS 49 Policy III.A requires that "each individual who receives or has custody of University cash and cash equivalents must be held responsible for cash and cash equivalents under his or her control." Policy VIII.A.2 states: "Individual accountability must be maintained and documented for all cash handling procedures;" and Policy IXA.3 states: "All cash transfers must be documented, and the documentation of accountability maintained by category."

Scrip was stored in a locked cabinet that was accessible by three clinic nurses. When scrip orders were received, staff verified that the scrip order was complete, and then listed scrip sequentially by serial number on a Scrip Issue Log, and stored it in a locked cabinet. When a scrip payment was needed, one of the nurses retrieved scrip from the locked cabinet, but did not record and initial the Scrip Issue Log to document the transfer out of scrip inventory.

The nurse recorded the scrip serial number on each subject's "Honorarium Log" and a recipient log, titled "List of Honorarium Checks." The subject signed both logs to document receipt of the scrip. The date of the scrip issuance was subsequently entered on Scrip Issue Log.

Because the Scrip Issue Log did not contain complete information, the Scrip Coordinator had to extract the disbursement information from the recipient log to complete the quarterly reconciliation for each scrip series, which was a time consuming process.

*Research Subject Payments – Scrip Management
Audit & Management Advisory Services Project 2011-34E*

Management Corrective Actions

FPM research unit management has:

1. Assigned the responsibility for distributing scrip to one person, and named a back-up scrip inventory manager to perform that function, as needed.
2. Implemented new procedures whereby scrip is recorded on the Scrip Issue Log when distributed to staff.
3. Modified the Scrip Issue Log to include additional columns for the subject identification code and subject initials to facilitate the reconciliation process.

B. Physical Security

The department's receptacle for storing scrip did not adhere to BUS 49 requirements.

BFS scrip issuance logs showed that for the period January 1, 2009 to September 10, 2010, the department was issued scrip orders that exceeded \$2,500 eleven times and scrip totaling \$1,001 to \$2,500 six times. The department stored its scrip in a locked cabinet. BUS 49, Section IX.5 states that "Each campus shall use lockable receptacles or burglarproof/fire resistant safes to store cash based on the following cash limits:

1. Up to \$1,000 in a lockable receptacle.
2. From \$1,001 to \$2,500 in a safe.
3. From \$2,501 to \$25,000 in a steel-door safe, with a door thickness of not less than 1 inch and wall thickness of not less than ½ inch.

Per BUS 49, deviation from these procedures may jeopardize the University's liability coverage.

Management Corrective Action

FPM research unit management has installed a safe to ensure compliance with BUS 49.

*Research Subject Payments – Scrip Management
Audit & Management Advisory Services Project 2011-34E*

C. Cash Handling Training

Staff responsible for handling scrip had not received cash handling training.

BUS 49 requires that staff handling cash and cash equivalents be trained on cash handling procedures. Because research unit personnel were not aware of this requirement, staff that handled scrip had not received this training.

Management Corrective Action

Research unit staff that handle scrip have completed online staff education in cash handling.

AMAS appreciated the cooperation received from research unit staff during the audit process. Because we have validated that all agreed upon process improvements have been implemented, additional audit follow up will not be required, and we consider this project to be closed.

UC wide policy requires that all draft audit reports, both printed and electronic, be destroyed. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel, or destroy them.

Stephanie Burke
Assistant Vice Chancellor
Audit & Management Advisory Services

Cc D. Brenner
M Caligiuri
R. Espiritu
G. Matthews
F. McCullough
A. McMahill
K. Naughton
T. Perez
D. Rico
S. Vacca