August 5, 2011

THOMAS KIPPS, M.D. Interim Director, Moores Cancer Center 0658

IRA GOODMAN Associate Director, Moores Cancer Center 0658

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

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 Moores Cancer Center. As part of our review, we examined the use of scrip for a specific project, titled *American Indian/Alaska Native Tobacco Study* (Study), which was managed by Principal Investigator Deborah Morton, Ph.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 was primarily the responsibility of the PI. The Fund Manager approved scrip orders and prepared financial ledgers.

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 PI and BFS staff:
- Analyzed the Study processes for ordering, issuing, returning, reconciling, storing and recording scrip; and,
- Reviewed documentation supporting the reconciliation of scrip for the sample Study for scrip issued January 1, 2009 through September 10, 2010.

### **Conclusion and Supporting Comments**

Based on our review procedures, we concluded that all scrip issued to intermediaries was accounted for. However, because all documentation was not available for review, we were unable to verify that payments to research subjects were made in accordance with an IRB approved research plan.

We noted that scrip issue logs were completed and copies of receipts issued to patients were retained. The Study involved conducting interviews with research subjects throughout the State of California. To facilitate Study activities in Northern California, the PI retained an intermediary to recruit research subjects and project interviewers. The PI obtained BFS approval to compensate both research subjects and interviewers using scrip. The PI delivered the scrip to the intermediary, and logged the transaction on a scrip log titled "Interviewer Receipt of Scrip from UCSD." The PI indicated that the intermediary also maintained a scrip log to record the scrip issued to pay the interviewers. Interviewers maintained a log of the scrip issued to research subjects, in addition to attaching a copy of the scrip receipt to a copy of the interview notes. In Southern California, the PI delivered scrip to contractors in two health clinics that assisted with conducting interviews. Those contractors maintained a log of scrip issued to research subjects. However, logs maintained by interviewers were not available for review during audit fieldwork.

While reviewing scrip documents, we determined that the quarterly reconciliation of scrip issued within the audit scope period had not been submitted to Disbursements. However, AMAS confirmed that the reconciliation was submitted in January 2011.

Opportunities for process improvements are discussed in more detail in the remainder of this report. Although this study has been discontinued, recommendations related to general BUS 49 and research compliance would pertain to future research projects conducted within the research unit.

## **Observations and Management Corrective Actions**

#### **A** Verification of Scrip Issued

Documentation was not available to support the reconciliation of scrip issued to research subjects.

The personnel who conducted research subject interviews logged subject scrip payments and issued receipts to the subjects. A copy of the receipt issued was returned to the PI with the completed research survey. The survey and receipt were filed together until the survey information was entered in to a database for analysis. The intermediary and interviewer logs were not returned to the PI. Because we were unable to review the logs, we could not verify that all scrip was issued to research subjects in accordance with an IRB-approved research plan.

### **Management Corrective Action:**

Moores Cancer Center management will ensure that a reconciliation of the scrip issued to project interviewers and research subjects to the Study scrip issue log has been completed.

### **B.** Segregation of Duties

# The research unit did not have adequate procedures to ensure separation of duties for scrip.

BUS 49 Policy II.B states, "no single individual is responsible for collection, handling, depositing and accounting for cash received by that unit." 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."

The PI was solely responsible for ordering, distributing, reconciling, and returning scrip.

## **Management Corrective Action:**

Moores Cancer Center management will implement new standard operating procedures for managing scrip which will address segregation of duties issues.

## C. Physical Security

## The research unit method of 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 on five occasions and scrip orders that exceeded \$25,000 on two occasions. The PI indicated that sometimes, she picked up scrip and delivered it to the intermediary; however, at other times, she stored scrip at her home. Scrip was stored in a locked receptacle; however, the receptacle did not meet the BUS 49 requirements.

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;
- 4. From \$25,001 to \$250,000 in a class TL-15 composite safe or better."

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

## **Management Corrective Action:**

Moores Cancer Center management will implement new standard operating procedures for managing scrip which will include scrip security procedures and will direct research units to plan individual scrip orders to ensure that scrip on hand does not exceed the BUS 49 \$1,000 lockable receptacle storage threshold.

# D. Cash Handling Training

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

BUS 49 requires that staff handling cash and cash equivalents receive training on cash handling procedures. Because Study personnel were not aware of this requirement, staff that handled scrip had not received this training. Additionally, Non-UCSD Study personnel in remote locations were not held to this requirement.

# **Management Corrective Action:**

Moores Cancer Center management will ensure that Cancer Center Fund Managers involved in handling scrip attend cash handling training as required by BUS 49.

AMAS appreciated the cooperation and assistance provided during the review. Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the corrective actions. At that time, we may need to perform additional audit procedures to validate that actions have been taken prior to closing the audit findings.

UC wide policy requires that all draft audit reports, both printed and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel, or destroy them. AMAS also requests that draft reports not be photocopied or otherwise redistributed.

Stephanie Burke Assistant Vice Chancellor Audit & Management Advisory Services

- cc: D. Brenner
  - M. Caligiuri
  - R. Espiritu
  - G. Matthews
  - F. McCullough
  - A. McMahill
  - J. Milner-Mares
  - K. Naughton
  - T. Perez
  - D. Rico
  - S. Vacca