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

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 Department of Psychiatry. As part of our review, we examined the use of scrip for a specific project, titled *A Randomized, Observer Blind, Placebo-Controlled, Four Way Cross-over Study to Study the Ability of Functional Magnetic Resonance Imaging of the Brain to Detect and Characterize the Effects of Single Doses of a Selective Serotonin Reuptake Inhibitor (Escitalopram [Lexapro®]), a Dopamine and Noradrenaline Reuptake Inhibitor and Psychostimulant (Methylphenidate [Ritalin®]), an Anti-glutamatergic Drug Candidate (mGluR5 Antagonist R04917523), and Placebo in Healthy Subjects (Study)*, which was managed by Principal Investigator Martin P. Paulus, 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.

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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 Psychiatry Study selected for review, scrip responsibilities were shared by a Study Coordinator; six staff members that assisted with distribution, record keeping and reconciliations; and a fund manager. The Fund Manager approves scrip orders and prepares 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 Study Coordinator;
- Analyzed the Study processes for ordering, issuing, returning, reconciling, storing and recording scrip; and,
- Reviewed documentation supporting the issuance of scrip for the sample Study.

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Conclusion and Supporting Comments

Based on our review procedures, we concluded that all scrip in the Study was accounted for and, with one exception; scrip was issued to research subjects in accordance with an IRB-approved research plan. We also noted opportunities to improve scrip management processes to ensure 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 generally ensure that scrip was issued to research subjects in accordance with the IRB-approved research plan. Staff responsibilities for receiving, issuing and reconciling scrip inventory were documented. 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. Although this study has been completed, 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. Compliance with Income Tax Requirements

Study participant compensation met the Internal Revenue Service (IRS) threshold for preparing Form 1099 to report payments to research subjects; however, subject tax identification information was not obtained.

The Study enrolled 25 research subjects. To comply with IRS regulations, research unit Scrip Coordinators are instructed to provide Disbursements with the information required to prepare tax documents for all subjects who receive more than \$600 in a given year. We noted that the Study research plan showed that subjects would receive up to \$1,250 in monetary compensation during a calendar year. For completing up to four optional tasks in the Study, the research plan indicated that subjects would earn an additional \$10 per task in retail gift certificates.

The research unit maintained a separate payment log for each Study participant. The logs verified that payments for each participant that completed the Study included \$1,250 in scrip plus at least \$10 in gift certificates during 2010. Additionally, Study subjects were provided meals because analysis of some drug therapies required the subjects to fast. The Study Coordinator stated that because the procurement of study participant tax identification data would have compromised the anonymity of the subjects, the research unit did not request that information.

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Management Corrective Actions

Research unit management has:

1. Worked with Disbursements to file 2010 1099 Forms as required.
2. Modified research unit procedures to ensure that required tax information is obtained from research subjects who receive payments that meet IRS reporting criteria.

B. Documentation of Extra Payments to Research Subjects

Research subjects sometimes received an additional payment that was not described in the study research plan.

The Study Coordinator stated that early in the study, if a research subject needed to return for laboratory tests, the Lead Researcher requested that the Study Coordinator pay the patient an extra \$20 in scrip, and this practice continued throughout the duration of the Study. The Study research plan and informed consent did not reference an additional payment.

The UCSD Human Research Protections Program has advised AMAS that instances of additional compensation paid, but not included in the research plan, should be submitted to the IRB for review to determine if additional action is needed. Because this Study has been completed, a revision of the research plan is not required.

Management Corrective Action

In the future, research unit management will document all research participant payments in the study research plan, and an amended plan will be submitted to the IRB if additional payments not referenced in the approved research plan are implemented while the study is in process.

C. Segregation of Duties and Accountability

The research unit did not have adequate procedures to ensure individual accountability and 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.” 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.”

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Scrip was stored in a locked cabinet. 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 with the scrip in the locked cabinet.

When a scrip payment was needed, the staff member who received and stored the scrip also disbursed it to the research subject. The scrip was removed from the locked cabinet, and entered onto a scrip log included in the subject's research file, which the subject signed to document receipt of the scrip. After the distribution was completed, the subject's study identification number and the date of scrip issuance were entered on the Scrip Issue Log. Because the Scrip Issue Log did not contain complete information about each transaction, the Scrip Coordinator had to reconcile the information on the Scrip Issue Log with the disbursement information recorded on each subject's scrip log to complete the quarterly reconciliation for each scrip series required by Disbursements.

In some cases, the Study required that research subjects come to the unit fasting for a blood test. The policy was to provide a meal or snack to the subjects immediately after the blood sample was obtained. We noted that the Study Coordinator purchased the meals for the subjects and subsequently prepared and approved a UCSD Payment Authorization to be reimbursed for that expense. Gift cards purchased to give to subjects for the optional portion of the study were also purchased by the Study Coordinator and the cost was reimbursed through a Payment Authorization.

We also noted that one former study staff member's duties included distribution of scrip, scrip ordering, preparing scrip for return, reconciliation of scrip and scrip certification. These duties have been assigned to a new staff member. To maintain a system of checks and balances one or more of these functions should be performed by different individuals.

Management Corrective Actions:

Research unit management will:

1. Assign the duties of distributing scrip to someone who does not also order, return and reconcile the scrip.
2. Require that scrip issues be recorded on the Scrip Issue Log when removed from scrip inventory.
3. Require that the Scrip Issue Log include the signature of the person issuing the scrip to the research subject for each transaction.
4. Work with the Psychiatry Business Office to ensure that Pay authorizations are prepared and approved by someone other than the payee.

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D. 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 to maintain an average scrip inventory of over \$1,000. The research unit stored 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:

Research unit management will take appropriate measures to secure scrip as required by policy. Alternatively, if possible, individual scrip orders will be reduced to ensure that the total scrip on hand does not exceed the BUS 49 \$1,000 lockable receptacle storage threshold.

E. 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.

Management Corrective Action

Research unit management has provided cash handling training to staff that handle scrip as required by BUS 49.

Audit & Management Advisory Services appreciates 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. While management corrective actions have been included in the audit report, we may determine that additional audit

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procedures to validate the actions agreed to or implemented are warranted. We will contact you to schedule a review of the corrective actions, and will advise you when the findings are closed.

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