



Payments to Human Subjects

Internal Audit Report No. I2013-106

July 11, 2013

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INTERNAL AUDIT SERVICES
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July 11, 2013

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RE: Payments to Human Subjects Audit
Report No. I2013-106

Internal Audit Services has completed the review of the Payments to Human Subjects and the final report is attached.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.

A handwritten signature in black ink that reads "Mike Bathke".

Mike Bathke
Interim Director
UC Irvine Internal Audit Services

Attachment

C: Audit Committee
Karen Allen, Director Human Research Protections

I. MANAGEMENT SUMMARY

In accordance with the fiscal year 2012-2013 audit plan, Internal Audit Services (IAS) reviewed the adequacy of internal controls and policy compliance for payments to human subjects at the University of California, Irvine (UCI). Business risks, control concerns, and compliance issues were identified. Specifically, the following issues were noted.

Human Subject Funds – Cash advances obtained to fund payments to human subjects were used to purchase cell phones and tablets for other University employees instead. This observation is discussed in section V.1.

Clearing of Cash Advances – Cash advance clearing documents lacked management review and approval. The lack of management review and approval of the clearing documents may have contributed to several risks and control concerns noted by IAS. These observations are discussed in section V.2.

Human Subject Compensation – Human subjects were not compensated in accordance with the approved protocol. This observation is discussed in section V.3.

Payments to Human Subjects Policies and Procedures – Researchers did not comply with University policies and procedures in managing funds used for compensation to human subjects. These observations are discussed in section V.4.

II. BACKGROUND

A human subject is an individual who becomes a participant in a research or clinical investigation. University policy provides that human subjects may receive benefits, financial or otherwise, for their participation in approved research projects. Human subjects may be compensated for their time, effort and expenses related to their participation in research. Compensation may be in the form of money, certificates, products, or other incentives. In some cases, payments are made to the parents or legal guardians of the participants.

The Principal Investigator (PI) conducting research which involves compensation paid to human subjects is responsible for ensuring that business processes and practices pertaining to payments comply with current university policy. The requirements are stated in the UCI Administrative Policy Section 701-03: Payments to Research Participants.

III. PURPOSE, SCOPE AND OBJECTIVES

The purpose of the audit was to review business practices and internal controls to determine if researchers were compliant with policy. Based on the assessed risks, the following objectives were established:

1. Review the study protocol to determine if the UCI Institutional Review Board (IRB) approved the method and amount of compensation to human subjects in advance;
2. Determine whether there were deviations in the amount, type or timing of the human subject payments as compared to the approved protocols;
3. Determine if internal records properly document all human subject payment transactions to include the following information: payment date, participant's signature acknowledging receipt of payment, subject ID code, payment amount, and the name of the person disbursing the payment;
3. Evaluate whether cash and cash equivalents used to pay human subjects were properly secured and physically protected from loss;
4. Determine whether personal bank accounts opened to maintain study funds were non-interest bearing checking accounts with the PI and the department chair or administrator named as account holders. In addition, a monthly reconciliation of the bank statements as well as a supervisory review approving the reconciliation performed by an individual who is not involved in the cash handling procedures were performed;
5. Verify if cash advances are cleared by completing the Certification of Payment to Anonymous Persons (CPAP) form and submitting it to the Accounting Office in a timely manner; and

6. Confirm if the total amount paid to a human subject during a calendar year is \$600 or more, the University reported such payments to the Internal Revenue Service as required.

IAS downloaded and analyzed all of the cash advances for human subject payments from July 2011 to July 2012 and selected the top four individuals/studies that received the highest total dollar amount of cash advances for review.

IV. CONCLUSION

IAS noted that the majority of the individuals interviewed (PIs, research coordinators, department administrators, etc.) were either not aware or not properly trained on the payments to human subject policies and procedures. In addition, several of the PIs and department administrators thought the current policies and procedures were unreasonable and unclear and needed to be reviewed and revised.

In addition to implementing the management action plans below, IAS recommends that management consider the following:

1. Setup a committee consisting of key stakeholders to review the current policies and procedures and make revisions to address the business risks and control concerns noted during the review;
2. The payments to human subject policies/procedures be a shared responsibility between the Office of Research Administration and Accounting and Fiscal Services to address both the human research aspects and disbursement/cash handling processes (currently the policies/procedures are owned by Accounting and Fiscal Services);
3. Include the compensation section of the approved protocol as supporting documentation for human subject cash advances so individuals approving and clearing cash advances are fully informed; and
4. Provide information and education on an ongoing basis to ensure involved individuals understand and implement the policies/procedures.

IAS noted several business risks and control concerns during the review. Observation details were discussed with management, who formulated action plans to address the issues. These details are presented below.

V. OBSERVATIONS AND MANAGEMENT ACTION PLANS

1. Human Subject Funds

Observation

IAS noted that one PI was requesting large cash advances (\$5,000 - \$10,000) for human subject payments related to his study. However, IAS found that the cash advances were not used to pay human subjects (and none had been enrolled at the time of the cash advances). Instead, the cash was used to purchase cell phones, tablets, accessories, and cell phone data plans/usage bills for multiple staff psychologists in the UCI Counseling Center. Human subject identification numbers were assigned to each of the staff psychologists, who were then reimbursed by the PI from the cash advance funds. The staff psychologists were required to sign human subject participant cash receipts that were then used as supporting documentation to the Certification of Payment to Anonymous Persons (CPAP) form submitted to clear the cash advances.

IAS questioned the PI about why he requested multiple cash advances for human subject payments, assigned identifiers to human subjects for anonymity, and used the cash advance funds to pay for cell phones, tablets, accessories, and cell phone data plans/usage bills when no one was enrolled to participate in the research. The PI stated that he was having trouble recruiting subjects so he reached out to the staff psychologists to help refer subjects to his study. He stated that he allowed the staff psychologists to purchase cell phones, tablets, accessories, and cell phone data plans so they could test the software application that was developed for use by human subjects. He did not have an explanation for assigning human subject identifiers to the staff psychologists and using the human subject cash advance funds to pay for the cell phones, tablets, accessories, and cell phone data plans/usage bills.

Improper accounting and use of human subject cash advances may cause audit disallowances, compromise future research funding, and risk unfavorable exposure to the University.

IRB Referral Action

IAS referred the observation to the Assistant Vice Chancellor for Research Administration, Office of Research (OR). It was determined that an IRB audit would be conducted by the OR/Human Research Protections and a financial review would be conducted by IAS. The results of those reviews (IRB Audit HS# 2009-6973 and IAS investigation report I2013-522) are not repeated within this report.

2. Lack of Management Review/Approval of Cash Advance Clearing Forms

Background

Cash advances are requested by the PIs, and then cleared using a CPAP form. In order to protect the anonymity of the subjects, CPAP forms are used which requires a human subject identification number (and not a subject name).

Observation

All of the CPAP forms reviewed lacked management review and approval. The lack of management review and approval of the clearing documents may have contributed to several risks and control concerns noted by IAS as follows.

- In one study, cash advanced funds were not used to pay human subjects but instead used to purchase supplies, materials, and equipment.
- In two separate studies, IAS noted that large cash advance amounts were requested but the funds were consistently unspent, only to be returned at the end of a four-month period. For example, in one study, a PI requested four consecutive cash advances (between \$15,000 - \$22,250 each) and returned on average more than \$12,000 in unused funds, with the largest returned cash advance over \$21,000. A review of the PI's bank account

revealed daily balances in excess of \$29,000. In another study, a PI requested a \$10,000 cash advance and returned over \$9,100.

The practice of frequently requesting large cash advance amounts is not a good business practice and increases the risks of inappropriate and unauthorized use of University funds when human subject enrollment activity is disproportionate to the cash advance amount requested.

Management Action Plan

IAS discussed the observations with each PI's management, who agreed that CPAP forms need to be reviewed and approved prior to clearing the cash advances and will do so in the future. Management was alarmed by the large cash balances on hand and the amounts of unused funds that were returned. Since Accounting requires that cash advances be closed within four months, PIs request new advances before closing the prior advance (for cash flow purposes), which in some instances, leads to large cash balances on hand.

In all instances, the original cash advances were appropriately reviewed and approved by management. However, since the CPAP forms are manual and most of the communication from Accounting about the open cash advance is directly with the PI, the clearing documents are not reviewed and approved by management.

IAS will follow-up in approximately six months (December 2013) to ensure the management action plan has been implemented.

3. Human Subject Compensation

Observation

Human subjects were not compensated in accordance with the approved protocol for one study reviewed. In addition to monetary compensation, human subjects received other incentives in the form of transportation and refreshments that were not approved in advance by the IRB.

The IRB evaluates and approves all forms of compensation to human subjects to ensure the amount, type, and method of remuneration is not coercive and is proportional to the inconveniences posed by participation in the study.

Management Action Plan

During the course of the review, the PI obtained, from the IRB, a modification to their approved protocol for additional compensation. This observation is considered closed and no further follow-up is necessary.

4. Payments to Human Subjects Policies and Procedures

Background

University administrative policy/procedure, 701-03, establishes guidelines for requesting, maintaining, documenting, clearing, etc. for funds designated in compensating human subjects.

Observation

IAS reviewed several cash advances for each of the four PIs and studies for appropriateness and compliance with policy. The following is a summary of the observations.

- Three of the four PIs had opened personal bank accounts to maintain study funds but did not have a department chair or administrator named as an account holder as required by policy. In addition, the fourth PI had set up a personal bank account with the department chair named as an account holder, but the department chair had retired in 2010.
- Several bank accounts were linked to interest bearing accounts which is prohibited by policy.
- In all four studies reviewed, monthly bank reconciliations were not performed. Per policy, checking accounts should be reconciled on a monthly basis.

- Signatures of research participants acknowledging receipt of payment were not always obtained, a required supporting document to the CPAP forms.
- Some cash handling duties were not properly separated. For example, a research coordinator with access to the office safe and online banking records was also disbursing payments to human subjects and completing the CPAP forms.

Those responsible for large cash advance amounts should establish procedures that ensure that no single individual is responsible for the collection, handling, depositing, and accounting for cash transactions in that unit. At least two qualified individuals should be assigned to carry out key duties of the cash handling process.

Management Action Plan

IAS discussed the observations with each PI's management, who will review the University policies and procedures with the PIs and ensure compliance.

IAS will follow-up in approximately six months (December 2013) to ensure the management action plan has been implemented.