

February 25, 2011

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***Subject: Conflict of Interest and Conflict of Commitment  
Audit & Management Advisory Services Project 2011-20***

The final audit report for Conflict of Interest and Conflict of Commitment Audit Report 2011-20, is attached. We would like to thank all departments for assisting in the review.

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 (copied on tan paper for ease of identification) 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, at this time.

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Attachment

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**AUDIT & MANAGEMENT ADVISORY SERVICES**



University of California  
**San Diego**

**Conflict of Interest and Conflict of Commitment  
February 2011**

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Project Number: 2011-20

*Conflict of Interest and Conflict of Commitment Faculty and Staff  
Audit & Management Advisory Services Project 2010-20*

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**I. Background**

Audit & Management Advisory Services (AMAS) has completed a review of UCSD processes for managing activities defined in selected University of California (UC) and UCSD Conflict of Interest (COI) and Conflict of Commitment (COC) disclosure policies in accordance with the approved annual audit plan for fiscal year 2010-11, and as part of a UC system-wide audit project. This report summarizes the results of our review.

COI Disclosure Requirements

Regulations promulgated by the Federal Government and the State of California, require UC to ensure that UC employees do not participate in business decisions in which they have a personal financial interest. A conflict of interest may arise when outside financial interests or other personal considerations compromise or have the appearance of compromising an employee's actions or judgments in the performance of work responsibilities. UC researchers may have a conflict of interest if outside financial interests compromise, or have the appearance of compromising, the researcher's professional judgment when designing research protocols, or conducting, and reporting research results. UC has established a Conflict of Interest Code to provide guidance to all employees on disclosing financial interests. Therefore, UC researchers are required to report financial relationships with research sponsors and donors to ensure that relationships are reviewed and monitored as needed.

Generally speaking, the process for disclosing possible conflicts of interest is initiated by the prospective receipt of extramural funds in support of UCSD teaching, research or clinical activities. Public or private research grants, clinical research agreements, commercial contracts or service agreements, gifts, and material transfer agreements require a COI disclosure. Conflict of interest disclosure forms have been implemented to identify financial or other business interests that require review and monitoring. The State of California and the Federal government have established different requirements for disclosure and review, and financial reporting thresholds. The California Fair Political Practices Commission requires that UC campuses use Form 700U to obtain information from the Principal Investigators (PI) on financial and other business relationships with the funding agency or donor.

To comply with federal regulations, University of California, San Diego (UCSD) created the 9510 disclosure form. Form 9510 must be completed by the PI and any other individual responsible for the design, conduct or reporting of the results of work performed or to be performed under the sponsored project. If a positive disclosure is made on either form, the Addendum to Investigator's Statement of Economic Interest must also be completed. The Addendum captures more detailed information.

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Financial interests reported on Forms 700U, 9510 or the Addendum include interests for the disclosing individual(s), their spouse and dependent children. The Form 700U must also be completed by a registered domestic partner. Signed disclosure forms are submitted in hard copy. Although the disclosure submission process is paper based, the results of the Conflict of Interest Office review are documented in UCSD systems.

UCSD Management of COI Disclosures

Each UC campus is required by policy and/or regulation to have an infrastructure in place to identify and manage conflicts of interest. The UCSD Chancellor established the Independent Review Committee (IRC) on Conflict of Interest in October 1982. The IRC reviews positive financial disclosure statements and relevant features of a research project, determines if a potential, perceived, or real conflict of interest exists by virtue of the reporting individual's financial interests, and advises the Chancellor about specific disclosures.

The UCSD Conflict of Interest Office, which reports to the Assistant Vice Chancellor of Research Affairs, assists all employees in evaluating situations under which their outside financial interests or other personal activities may compromise or have the appearance of compromising their actions in the administration, management or performance of their professional activities at UCSD, in accordance with UCSD PPM 200-13, *Conflict of Interest*. During Fiscal Year 2009-10, the UCSD Conflict of Interest Office processed approximately 5,500 disclosure statements. Potential conflicts of interest are reported on only about one percent of the disclosure statements received by the Conflict of Interest Office.

OCGA and the Health Sciences Sponsored Project Pre-award Office (HSSPPO) input PI, Co-PI, co-investigator and other personnel data into the UCSD integrated grant and contract proposal and award system, COEUS. To assist with the management of disclosure data and IRC activities, the Conflict of Interest Office maintains an internal database which is housed on the department server and is interfaced to COEUS. Selected COEUS proposal data is downloaded to the COI database on a nightly basis. The COI Director uses this data to identify the disclosures that have been submitted as part of the research proposal package. Additional inquiries are made if expected disclosures are not received.

UC COC Disclosure Requirements

Academic Personnel Manual (APM) Policy 025: *Conflict of Commitment and Outside Activities of Faculty Members* describes the UC policy on conflict of commitment and outside professional activity for faculty members. The policy outlines the faculty responsibilities for obtaining approval and disclosing compensated and uncompensated outside activities.

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A full-time faculty member on an academic-year appointment is limited to 39 days of compensated outside professional activity from the start of the fall term through the end of the spring term. Fiscal-year appointees are limited to 48 days during the months of active service. Exceptions to these limits may be approved by the Chancellor. Compensated outside professional activities are classified in three categories, based on the extent to which they may potentially raise conflict of commitment issues, as follows:

- *Category I* activities are likely to raise issues of conflict of commitment and require prior written approval before the faculty member may engage in the activity. Examples of Category I activities include assuming an executive or managerial position in an outside entity, establishing a relationship as a salaried employee outside the University, compensated teaching or research at another institution while employed as a full-time faculty member at the University, or administering a grant outside the University.
- *Category II* activities are less likely to raise issues of conflict of commitment and are ordinarily allowed without prior approval. Examples of Category II activities include consulting, serving on a board of directors, providing a workshop for industry, and providing expert testimony.
- *Category III* activities ordinarily do not raise conflict of commitment concerns, are considered part of the faculty's scholarly and creative work, and do not count toward the 39/48-day limits. Examples of Category III activities include serving on government committees, serving as editor of a professional journal, reviewing journal manuscripts or grant proposals, and developing scholarly works such as books, journal articles, movies, or television productions.

UCSD Management of Category I Pre-Approval – General Campus

Eligible campus faculty who anticipate Category I involvement in the coming academic year must prepare a *Request for Approval of Category I Activity* form and submit it to their Department Chair(s) for review. The Department Chair completes the initial review and provides a recommendation, which is then forwarded to the campus Divisional Dean for review. The Dean has approval authority for all prior approval requests for Category I activities except for administration of a grant outside of the University, or compensated teaching or research at another institution while employed as a full-time faculty member at the University. In cases of compensated teaching or research at another institution, the Dean provides a recommendation and the request is forwarded to the Senior Vice Chancellor for Academic Affairs for final approval. If the Category I request is for administering a grant outside of the University, the Dean forwards the request with his or her recommendation to the Vice Chancellor for Research, who provides a recommendation and forwards the request to the SVCAA for final approval.

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UCSD Management of Category I Pre-Approval – Health Sciences

Eligible faculty who anticipate Category I involvement in the coming academic year must prepare a *Request for Approval of Category I Activity* form and submit it to their Department Chair(s) for review and approval. The Department Chair reviews Category I requests based on established criteria, makes a recommendation for approval, and forwards the request form and supporting documents to the Health Sciences Associate Dean of Academic Affairs (Associate Dean) for evaluation. After reviewing the request, the Associate Dean forwards all documents to the Health Sciences Compliance Advisory Group (CAG). The CAG notifies the Associate Dean, the Department Chair and the faculty member of its approval or disapproval of the request. After action by the CAG, all requests and related correspondence on Category I activities are forwarded to the Associate Dean for Academic Affairs and copies are filed in the faculty member's official record.

If a request for participating in a Category I activity involves a partial or full leave of absence, the *Academic Leave of Absence/Sabbatical* form must be submitted to the department chair along with the request. This is the case for all faculty, including those in Health Sciences.

UCSD Management of Annual Disclosures

All faculty members must also disclose actual time spent on compensated Category I and Category II activities annually via the "*Report of Category I and Category II Compensated Outside Professional Activities and Additional Teaching Activities*" (Annual Reports). This report is due each November 1 for the prior fiscal year's activity. Annual Reports are retained in the faculty member's department. The Department Chair is relied upon to recognize a potential conflict, with advice from department support staff, the Dean's office and the Academic Personnel Office (APO) as needed.

Management of COI or COC

Potential conflicts that surface based on a Category I activity request or the Annual Report are managed on a case-by-case basis.

**II. Audit Objective, Scope, and Procedures**

The objective of our review was to assess the adequacy of internal controls in campus conflict of interest and conflict of commitment management processes, and overall compliance with University policy. The scope of the audit focused on COI disclosure documentation associated with federally and commercially sponsored contracts or grants active during FY 2009-10; and COC disclosures for FY 2009-10.

In order to achieve our objectives, we performed the following procedures:

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- Reviewed relevant university and campus policies, procedures and Federal regulations related to COI and COC disclosure requirements;
- Interviewed key personnel to gain an understanding of campus processes for submitting, evaluating and monitoring COI and COC disclosures;
- Reviewed delegations of authority for approvals under APM 025;
- Analyzed a judgmental sample of disclosure statements related to commercially sponsored research awards active during FY 2009-10;
- Evaluated a judgmental sample of disclosure statements related to Federally sponsored research awards active during FY 2009-10;
- Evaluated a judgmental sample of positive disclosures related to Forms 700U for Federal research awards active during FY 2009-10;
- Reviewed all FY 2009-10 requests for pre-approval submitted to the Chancellor's designees to engage in Category I (Compensated Outside Professional) Activities;
- Evaluated a judgmental sample of FY 2009-10 faculty annual reports of Category I and II compensated outside professional activities and additional teaching activities; and,
- Traced a judgmental sample of requests for pre-approval submitted to the Chancellor's designees to engage in Category I to related disclosure statements.

UC and campus policies and processes for managing employee/vendor relationships, the hiring of near relatives, patent and technology transfer and use of University resources, Health Sciences Compensation Plan outside income, and conflicts of interest or commitment for members of the Senior Management Group were excluded from the scope of this review.

**III. Conclusion**

Based on the audit work performed, we concluded that internal controls in campus conflict of interest and conflict of commitment management processes were generally adequate and provided reasonable assurance that disclosures were obtained as required by University policies and procedures. Audit testing confirmed that processes for prior approval of Category I outside professional activities, annual disclosure of compensated outside professional activity, and faculty leaves related to outside professional activities were appropriately administered. We also noted that due to significant effort on behalf of

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UCSD faculty, departments and administrative offices, the level of compliance with COC disclosure requirements was generally high. However, disclosure submission processes were manual and complex, requiring a significant dedication of staff resources.

We also noted opportunities for improvement to COI/COC disclosure submission and management processes, and the need for policy clarification, which are discussed in more detail in the remainder of this report.

**IV. Observations and Management Corrective Actions**

**A. Disclosure Form Submission Process**

**The current disclosure form submission process is paper-based and complex.**

The current disclosure submission process is manual and requires significant staff resources in UCSD administrative offices and departments to ensure that COI disclosure forms 700U, 9510 and the Addendum; and COC annual disclosures are obtained and reviewed by appropriate parties based on established requirements.

In addition to being resource intensive, the paper-based disclosure processes are prone to the misplacement of documents. COI and COC disclosure submission processes facilitate the routing of thousands of documents through various offices and approval processes each year. The majority of the disclosure statements generated at UCSD each year only serve to convey negative disclosures, i.e. to document the *absence* of a related financial interest or outside professional activity. Negative disclosures are an important component of the control process. However, the collection of negative disclosures is resource intensive and cumbersome.

During the audit, we inquired whether the campus had considered automating the disclosure submission process to improve compliance, timeliness, and reduce the level of resources needed to manage the document flow. COI has partially automated the process by entering its review results into several systems, including the HRPP system and COEUS and interfacing that information into a database maintained on the COI department server. California Government Code Section 81008 states that disclosures filed pursuant to the Fair Political Reform Act of 1974 are subject to public inspection. Section 81009, Subsections (e) and (g) require that original, signed 700U forms be retained for a period of no less than seven years. However, procedures further state that after an original report or statement or a copy has been on file for at least two years, the officer with whom it is filed may comply with Section 81009 records retention requirements by retaining a copy on microfilm or other space-saving materials available for public inspection instead of the original report or statement or copy.

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The development of a system that would allow all COI and COC disclosures to be input into a secure database and electronically signed could result in complete, accurate information that could be accessed by COI, the APO and Health Sciences administration for evaluation and additional review as needed. The campus has identified the Quali Coeus (KC) Conflict of Interest module for this purpose. AMAS was advised that when fully implemented, this system could provide for electronic input and management of COI information from a variety of sources. However, we understand that the necessary resources to implement Quali Coeus COI module have yet to be identified.

**Management Corrective Actions:**

1. The campus should continue to pursue the implementation of the KC COI module in order to permit the consolidation of disclosure information for ease of verification by researchers, and electronic access to this information by multiple offices.
2. Campus management will continue to work with the UC Office of the President to identify ways to improve the efficiency of all processes that capture conflict of interest information, including faculty conflicts of commitment, designated officials reporting and researcher conflicts of interest disclosures.

**B. Completeness of Federal COI Disclosure Information**

**COI did not have a system in place to monitor whether all COI disclosures were submitted on federal awards. In addition, UC policy should be clarified to provide consistent guidance on which study personnel must disclose and are considered to have sufficient responsibilities for research design, conduct and reporting.**

**Identification of Personnel Required to File Disclosures**

Although the PI is currently responsible for identifying personnel responsible for research project design, conduct or results reporting, the PI is not currently required to document this determination. The Request for Extramural Support (RES) form required for each research proposal identifies Co-PIs and co investigators, but it does not include the other project personnel that, by definition, should submit a disclosure. As a result, the Conflict of Interest Office does not have the information necessary to compare the disclosures required to disclosures received for each federal research project.

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Policy and Guidelines Interpretation

UC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects, and Federal Regulation 42CFR50.603 each includes the following definition:

*“Investigator” means the Principal Investigator or any other person who is responsible for the design, conduct, or reporting of research funded by the Public Health Services (PHS) or proposed for such funding. For purposes of this subpart relating to financial interests, “Investigator” includes the investigator’s spouse and dependent children.*

UC campuses have typically allowed the PI to determine which personnel on the project met that definition. However, lack of UC guidance regarding the interpretation of which personnel are required to disclose has caused difficulty with ensuring that UCSD is meeting federal disclosure guidelines.

UCSD guidelines for the submission of federal COI disclosures (Form 9510) require that disclosures be provided by all personnel who are responsible for the design, conduct and reporting of research on any project covered by the federal COI disclosure requirement as determined by the project PI. AMAS selected a judgmental sample of 10 active PHS funded research projects from COEUS, and requested the 9510 disclosure forms from the Conflict of Interest Office. We found that PIs consistently filed the Form 9510. However, Co-PIs did not file Form 9510 for four of the 10 projects in the sample. Because a consistent process has not been defined, it could not be readily determined whether UCSD was in compliance regarding COI disclosures from these four Co-PIs. The lack of a systematic process for documenting the individual PI decisions makes it difficult and impractical to routinely verify that all required disclosures have been submitted, which increases the risk of non-compliance with federal regulations.

During the audit fieldwork we learned that as part of the new NIH FCOI regulations, the agency will issue guidance on the study personnel meeting the definition of who is considered to be “responsible for the design, conduct and reporting” of PHS-funded research. In addition, we understand that UCOP is working on a proposed definition in advance of the implementation of an eCOI reporting system. When available, these enhanced policy definitions should also help to ensure that all required disclosure forms are submitted in accordance with university and sponsor policies.

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**Management Corrective Actions:**

1. Form 9510 has been revised to require the PI to specifically state which personnel are required to submit a COI disclosure. The revised Form has been designed and approved by the IRC. It will be implemented after new NIH regulations are released.
2. The Vice Chancellor of Research will continue to work with UCOP to clarify UC policy regarding the definition of which sponsored project personnel are considered to be “responsible for the design, conduct and reporting” of sponsored research for the purpose of COI disclosures.

**C. APM 025 Policy Requirements**

**Audit interviews indicated the following areas of APM 025 that were unclear, difficult to interpret, and could result in potential inconsistent application of the policy.**

*Category I and Category II Activities:* Academic divisions reported that a clearer distinction between Category I and Category II activities would be helpful in interpreting policy requirements. In particular, policy language regarding consulting activities was considered to be confusing. APM 025 indicates that consulting is a Category II activity when the activities are “provided by the faculty member acting as an individual, or are provided by the faculty member through his or her single member professional corporation or sole proprietorship.” However, the policy further states that should a faculty member plan to provide such services through another type of organization or arrangement, the activity would be considered to be Category I and prior approval would be needed. This language may be confusing to faculty and support staff because the faculty may not have a separately established professional organization or sole proprietorship, but also may not feel that they are acting as an individual because they are using their expertise developed through University work and research as a basis for the consulting efforts. As a result of this confusion, faculty members often submit requests for prior approval of activities that are actually Category II, resulting in unnecessary administrative workload in evaluating these forms.

*Leaves of Absence:* Division staff indicated that the approval and disclosure requirements for the outside professional activities of faculty members on unpaid leave of absence were unclear. APM 025 states that “in order to engage in [Category I] activities while an active member of the faculty” the faculty member must obtain written approval in advance of the activity. The UC Office of the President advised in the past that faculty on an approved 100% leave of absence

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from the University were not “active” faculty, and therefore prior approval for any Category I activity engaged in during the leave period was not required. In those cases, approval for the leave of absence was obtained, and the reason for the leave was evaluated at that time. However, because the faculty member was on leave before participating in Category I activities, a separate approval was not obtained. In addition, local policy interpretation was that 39/48-day time limits and annual reporting requirements also did not apply to faculty on leave of absence.

*Policy Applicability & Enforcement:* Local officials noted that faculty members with Senior Management appointments may have difficulty identifying the appropriate relationship between the APM 025 policy and the Senior Management Group policy on Outside Professional Activities, and his or her obligations under each policy. Concern was also raised that APM 025 applies only to faculty, and not to individuals appointed in the Researcher series, who may have similar involvement in outside professional activities. Also, APM 025 does not outline consequences for non-compliance, which makes it difficult for academic administrators to fully enforce the reporting requirements.

The issues described above cause difficulty for academic administrators, and the support staff who advise them, in interpreting the intent of the policy and communicating these requirements to faculty. This lack of clarity may also impact the faculty’s confidence in academic administration’s ability to understand and implement the administrative policies applicable to faculty members. Consideration should be given on a system-wide basis to these potentially confusing aspects of the policy.

**Management Corrective Action:**

The UC Committee charged with the revision of APM 025 will consider whether the issues identified can be further clarified during the policy revision process.

**D. APM 025 Policy Compliance**

**AMAS noted limited instances of non-compliance with the terms of APM 025.**

AMAS reviewed FY 2009-10 Annual Reports for a judgmental sample of 116 faculty members required to submit an APM 025 disclosure<sup>1</sup>, which represented five percent of the 2,319 UCSD faculty members who were required to file an

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<sup>1</sup> The sample of 116 forms was selected using a judgmental sampling approach. It consisted of 116 faculty members who were chosen from a listing of all ladder-rank faculty members.

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annual report in FY 2009-10. The 116 faculty members were selected from 42 different UCSD campus and Health Sciences departments.

Thirty two of the 42 departments (76%) were found to be fully compliant with the APM 025 annual reporting requirement. The remaining 10 departments had not received one or more of the sampled FY 09-10 faculty annual reports in the sample when audit fieldwork was completed.

For the 10 departments not in full compliance, several factors impacted the failures to complete the required COC annual reports. In 6 of the 10 departments, the annual request for the forms were not sent out to faculty members on a timely basis or were not sent out at all. In 3 of the 10 departments, individual faculty members had not submitted an annual report despite several reminders. Finally, in one department a faculty member on recall status did not receive a request to file based on the administrator's misunderstanding that the report was not required.

Failures to file the required annual COC reports apparently went undetected due to the lack of a comprehensive, UCSD-wide system for monitoring report submission status. Another contributing factor in some departments was the lack of a process for escalating instances where annual reports have not been submitted after several requests.

The School of Medicine (SOM) as a whole was an exception. Rigorous systems for monitoring and escalating past due reports have been implemented. As a result, the SOM experiences extremely high levels of compliance with the APM 025 requirements. However as of the time of our audit fieldwork not all UCSD departments had such systems in place.

As a result of the exceptions above, some compensated outside professional activity may not have been accurately disclosed, or the disclosures did not receive sufficient review by department personnel.

**Management Corrective Actions:**

The APO will:

1. Reinforce to academic divisions their responsibility for ensuring that Annual Reports are submitted on time and filled out completely.
2. Implement procedures to ensure that secondary review of Department Chair Annual Reports is completed.

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**E. Coordination of COI and COC Report Information**

**Category I COC disclosure information reviewed by the campus APO was not forwarded to the Conflict of Interest Office.**

A prior AMAS audit, *Conflict of Commitment*, Project #2007-07 identified the need for the campus APO to share information related to faculty compensated outside professional activities with the Conflict of Interest Office.

The Health Sciences CAG reviews all faculty Category I activity requests, and as a member of the CAG, the Conflict of Interest Director obtains related information for Health Sciences faculty. However, the Conflict of Interest Office does not have access to information in campus COC disclosure statements. This information would be especially useful in identifying and evaluating potential conflicts related to both the compensated outside professional activity and extramural contracts or grants.

Additional coordination between the campus APO and the Conflict of Interest could improve institutional evaluation of conflict of interest issues.

**Management Corrective Action:**

The Academic Personnel Office and the Conflict of Interest Office will establish procedures to provide information obtained on Category I approvals to the COI Office to assist with evaluating potential conflict of interest issues that arise related to extramurally funded research.

**F. COI Policy Update**

**The latest draft revision of UCSD PPM 200-13, *Conflict of Interest* has not been finalized.**

The prior version of this policy and procedure document was published in 1984 and is no longer current. AMAS was provided with a draft copy of the revised policy, but we determined that it has not yet been published due to unavoidable delays in the approval process.

**Management Corrective Action:**

The Conflict of Interest Office will facilitate the publication of the revised COI as soon as final approval is received.

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**G. Retention of COI Disclosure Forms**

**Copies of COI disclosure forms could not be located in Conflict of Interest files.**

AMAS requested that the Conflict of Interest Office provide copies of a judgmental sample of 29 COI disclosure forms for focused review. Seven of the 29 documents requested could not be located in the files.

The COI Analyst stated that because the COI database indicated that each of the missing disclosures had been received and reviewed, those documents could have been lost when sent to a vendor to have them scanned or during the relocation of COI offices.

Copies of the missing documents may be available in other UCSD locations. However, the Conflict of Interest Office has been designated as the office of record. Failure to maintain copies of these documents in the COI Office could result in disclosures not being readily available when requested by external auditors.

**Management Corrective Action:**

The COI office is in the process of implementing a document management system.