

Individual Conflict of Interest in Research Policy

October 2017

FY17 - #04

Submitted to:

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Summary

Our audit of compliance with Policy Res-101 *Individual Conflict of Interest in Research (ICOIR)* was included in our approved Fiscal Year (FY) 2017 Audit Plan. The University of Arizona's (UA) strategic goals encourage research innovation and entrepreneurial activities that can lead to the potential conflicts of interest addressed in this policy. While this is our first audit of compliance with this policy, we concurrently conducted an audit of compliance with Policy Res-102 *Institutional Conflict of Interest* that will be issued as a separate report.

Background: UA implemented the current conflict of interest policy and procedures in 2014 in response to changes to the National Science Foundation's (NSF) terms and conditions for federal awards. Because UA receives federal awards from many federal agencies that adopt NSF terms and conditions, UA determined that the policy would be applicable to all federal and sub-federal awards, as well as any non-sponsored research performed by faculty and other employees. Following an interim policy version, the current policy became effective as of May 21, 2014.

According to the *ICOIR* Purpose section, UA is "dedicated to maintaining high standards of objectivity, integrity, credibility, and ethical conduct in the conduct of its research and research-related activities, including sponsored research services, research contracting, technology transfer, research compliance, and research administration." One part of this is understanding that employees may "engage in many relationships with external entities, some of which could have a direct relevance to his/her UA research, academic, and/or administrative responsibilities." As such, UA implemented the Conflict of Interest Program (COIP) to ensure that the potential conflicts are disclosed and monitored as needed.

COIP oversees compliance with *ICOIR* and includes a Conflict of Interest Officer and support staff. COIP's compliance activities include outreach to educate employees, preparation of the required training, maintenance of the COIP information system that holds disclosure and training information, assistance to the Institutional Review Committee (IRC), and administration of management plans. COIP falls under UA's Office for Research, Discovery and Innovation, led by the Senior Vice President for Research (SVPR).¹

COIP provides outreach to campus departments, researchers, and leadership to increase awareness of the policy and provide information about how to comply. In addition, Sponsored Projects and Contracting Services (SPCS) has steps built into their award process to ensure that key personnel complete the COI training and disclosure as needed.

¹ Subsequent to completion of audit fieldwork, the structure changed and the area is now led by the Interim Vice President for Research.

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Under the policy, researchers must complete training on the COI regulations, policies and procedures every four years.² Following completion of training, they are automatically granted access to the COI system to input any financial interests.

The COIP information system was developed by UA staff to track training and disclosures. Researchers are able to enter their own disclosure information, which can then be viewed by COIP to determine whether further review is needed.

If an investigator discloses a financial interest and COIP staff determine that the interest is clearly unrelated to the employee's research, then no further review is needed. If a financial interest is not clearly unrelated to the investigator's research, COIP refers the matter to the IRC. The IRC is comprised of at least 10 faculty members who review details of disclosures to determine whether there is a financial conflict of interest (FCOI). If a FCOI is identified, the IRC recommends a plan to manage the FCOI to the SVPR.

Besides UA employees, subrecipient organizations may be subject to UA's *ICOIR* policy. As part of the subaward process administered by SPCS, subrecipient organizations must either certify that they have a compliant conflict of interest policy and process or agree that their investigators on the subaward will comply with UA's policy.

Audit Objective: Our primary audit objective was to determine whether practices were in compliance with *ICOIR*.

Scope: Our scope included internal controls in place between April and October 2017. For certain controls, we sampled transactions that occurred during FY 2017. Our scope did not include evaluating whether UA's policy was in compliance with the federal NSF guidance.

Methodology: Our audit objective was accomplished by performing the following:

- Performing a preliminary review of the policy, including gathering information on the policy-making process, and gathering general information from UA's Research Gateway website regarding the COIP.
- Reviewing COIP presentation documents, informational brochures, and other methods COIP uses to educate campus administrators, leaders, researchers, and employees about the *ICOIR* policy.
- Reviewing the training document and disclosure information provided to investigators.

² During audit fieldwork, the training was an online document that University Administrators read and then certified that they had completed the training. In calendar year 2018, the training was updated to be an interactive e-learning course.

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- Discussing procedures with COIP staff to identify existing internal controls to ensure all employees and subawardees covered by *ICOIR* are in compliance.
- Selecting a sample via blind pencil stab of ten completed training certification and disclosure records in the COI system and performing the following:
 - Reviewing the information to confirm the system was functioning as intended, and
 - Ensuring COIP staff reviewed when needed and documented the review in the system.
- Selecting two monthly IRC meetings from FY 2017, reviewing meeting materials and committee documentation, and performing the following:
 - Tracing the information related to specific disclosures from the two meetings to the COI system to ensure disclosure review and status was documented accurately.
 - Selecting two financial conflict of interest disclosures reviewed by the IRC during the sampled meetings that were recommended for a management plan to ensure that the management plan was developed and monitored.
- Meeting with the former Vice President (now retired), Assistant Vice President, and Director for Tech Launch Arizona (TLA) to identify how COIP and TLA work together to ensure employees are aware of the *ICOIR* policy and encourage compliance from early in the startup process.
- Meeting with the following SPCS staff to identify procedures related to compliance with the *ICOIR* policy:
 - Assistant Director,
 - Manager,
 - Sponsored Projects Administrator Senior,
 - Sponsored Projects Administrator, and
 - Contract Analyst.
- Selecting a sample via blind pencil stab of 10 vendors from the approximately 300 vendors paid as subrecipients in FY 2017 and performing the following:
 - Viewing subaward files maintained by SPCS to identify the subrecipient's method of COI compliance, and
 - Confirming the information was obtained prior to award or renewal of the subaward.

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- Discussing COIP information system access provisioning procedures and electronic record retention with the Conflict of Interest Officer.
- Obtaining a list of users with administrative access to the COIP information system and determining whether the access was still necessary.
- Discussing controls over the COIP information system with the Senior Application Developer to determine the development process for the system, how business rules are initiated and modified in the system, and back-up and maintenance controls.

Conclusion: The audit identified a number of practices that were in compliance with the *ICOIR* policy as well as three opportunities for improvement to better encourage and document compliance, described later in the report.

- COIP has developed procedures to efficiently gather employee disclosures of significant financial interests, review the disclosures for referral to the IRC, and monitor resulting management plans.
- COIP staff provide outreach and communication about the policy to the campus community to ensure investigators are aware of the requirements and to encourage compliance with the policy.
- There are several strong internal controls built into the federal award process due to collaboration between COIP and SPCS. Data from UAccess Research is pulled into the COI system so that Key Personnel listed on funding requests are notified of the *ICOIR* training and disclosure requirements before the expected start date of their research project. Then before finalizing an award, SPCS checks for completion in the COI system and notifies COIP if all are not completed. For certain critical federal agency awards, SPCS holds the award until compliance is achieved.
- COIP works closely with TLA to promote COI compliance among UA employees licensing Arizona Board of Regent-owned intellectual property (IP). Discussions take place early in the licensing process to ensure potential conflicts of interest are identified and addressed. Additionally, a TLA representative attends all IRC meetings as a non-voting member and sometimes assists the COI office by advising on preparation of management plans.
- There were reasonable controls to ensure the COI system was functioning as needed and that only authorized users were granted access. However, the system was originally built to be temporary, but is still in use three years later. According to COIP management, work has begun to implement the conflict of interest management module of Kualu Research as part of the UAccess Research system.

We also identified several minor issues that were provided to COIP management verbally during the audit.

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According to the Institute of Internal Auditors International Professional Practices Framework, an organization is expected to establish and maintain effective risk management and control processes. These control processes are expected to ensure, among other things, that:

- The organization's strategic objectives are achieved;
- Financial and operational information is reliable and possesses integrity;
- Operations are performed efficiently and achieve established objectives;
- Assets are safeguarded; and
- Actions and decisions of the organization are in compliance with laws, regulations, and contracts.

Our assessment of these control objectives as they relate to compliance with the *ICOIR* policy is presented on the following page.

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General Control Objectives	Control Environment	Audit Result	
		No.	Page
Achievement of the Organization's Strategic Objectives			
<ul style="list-style-type: none"> COIP practices promote compliance with the policy and further UA's strategic objective to encourage research innovation and entrepreneurial activities. 	Reasonable to Strong Controls in Place		
Reliability and Integrity of Financial and Operational Information	Not Applicable		
Effectiveness and Efficiency of Operations			
<ul style="list-style-type: none"> COIP information systems are protected and functioning. 	Reasonable to Strong Controls in Place		
<ul style="list-style-type: none"> Procedures are communicated to campus employees to promote compliance. 	Reasonable to Strong Controls in Place		
<ul style="list-style-type: none"> Employee disclosures of significant financial interest are reviewed and management plans are monitored. 	Reasonable to Strong Controls in Place		
Safeguarding of Assets	Not Applicable		
Compliance with Laws and Regulations			
<ul style="list-style-type: none"> Practices are adequate to ensure compliance with the policy. 	Opportunity for Improvement	3	11
<ul style="list-style-type: none"> Documents supporting compliance with the policy are adequately safeguarded, maintained, and disposed of in compliance with records management policies. 	Opportunity for Improvement	1	7
<ul style="list-style-type: none"> Actions of the Institutional Review Committee are in compliance with policy. 	Opportunity for Improvement	2	9

We appreciate the assistance of UA employees during this audit.

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Audit Results, Recommendations, and Responses

1. Record retention periods have not been reviewed.

Condition: COIP does not have written procedures for maintaining, archiving, and destroying records created in conjunction with compliance with *ICOIR* policy. In addition, there are no defined retention periods for the documents created.

COIP creates and maintains documentation of compliance with the policy, including the following documents, whether electronic or hard-copy:

- Records of training completion and disclosure of significant financial interests by employees;
- Minutes of the Institutional Review Committee; and
- Descriptions of Management Plans, including committee members and information about ongoing monitoring.

Criteria:

- UA's Records Management and Archives (RMAA) website states that UA subscribes to the Arizona Revised Statutes (A.R.S.) definition of a record. A.R.S. § 41-1350 states that "Records are: all books, papers, maps, photographs, e-mail, or other documentary materials, regardless of physical form or characteristics...made or received by the University in the pursuance of law or in connection with the transaction of public business and preserved....as evidence of the organization, functions, policies, decisions, procedures, operations, or other actions of the University."
- The RMAA website further states that all records must be retained in a readable format and that the owning department is responsible for ensuring that electronic materials remain readable and retrievable.
- Good business practice suggests that record retention procedures be documented to increase compliance and ensure consistency when there is department turnover.

Cause: The Conflict of Interest Program believed they were following UA records management standards, but had not evaluated how their records would be stored or what specific category their records fall under to determine the retention period.

Effect:

- Documents may not be maintained in a readable manner or may be inadvertently deleted prior to the end of the retention period.

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- Records in a system may not remain accessible if a new system is implemented and the prior system becomes outdated.
- Procedures may not be in compliance with A.R.S. or UA policy.

Recommendations:

1. Work with RMAA to identify the retention period(s) for the applicable records.
2. Determine whether records will be maintained as electronic, paper, or both. For electronic records, determine how they will be maintained and how COIP will ensure the format remains readable for the duration of the retention period.
3. Develop specific procedures to document how the retention process will be handled, including who is responsible for records maintenance and disposal.

Management Response: Target Implementation Date: July 2019.

On November 13, 2017, COIP met with the Office of General Counsel (OGC) to discuss COIP's retention policy. Legal counsel indicated that COIP's documents fall under a number of categories making it difficult to select one retention schedule that would be applicable to COIP. As such, a determination was made to retain all documents indefinitely while the retention policy is under review and to proceed to convert paper documents and to develop a document management system. COIP began converting paper documents in Spring 2018 and expects to have an OGC and RMAA-approved retention period no later than July 2019.

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2. The IRC does not have an approved, written charter.

Condition: The IRC is integral to UA's ability to comply with its *ICOIR* policy, but the committee does not have a written charter or another committee-approved document that describes the procedures for the committee, including:

- Powers of the committee chairs, including pre-meeting "triage" and decision-making authority;
- Who is responsible for monitoring committee membership;
- Whether retired/emeritus UA employees qualify to be members of the committee;
- Procedures for voting (i.e., individual vocal voting vs. consensus agreement); or
- Who is responsible for maintaining the meeting minutes following committee approval.

Criteria:

- Good business practices suggest that committee procedures be approved and documented to ensure consistent application.
- Policy Res-101 *Individual Conflict of Interest in Research* states that committee members "should be active researchers with an understanding of research practices and activities within their respective disciplines."

Causes:

- The IRC chairs and the Conflict of Interest Officer had established practices to ensure the IRC worked efficiently but, due to the workload, the procedures had never been written or formally approved by the IRC.
- COIP and the IRC believe that emeritus faculty clearly meet the requirements of the policy and, therefore, did not think that documentation was necessary.

Effect:

- Powers of the chair(s) may not be consistently understood and applied by the committee members or the COIP.
- Committee membership may not be in compliance with *ICOIR*.
- Voting procedures and meeting minutes may not be consistent.
- It is not clear whether emeritus faculty are permitted to be IRC members.

Recommendation: The COIP should work with the IRC to develop and approve a committee charter or another written document that specifies committee procedures and authority. The document may include:

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- Powers of the committee chairs, including pre-meeting "triage" and decision-making authority;
- Who is responsible for monitoring committee membership;
- Whether retired/emeritus UA employees qualify to be members of the committee;
- Procedures for voting (i.e., individual vocal voting vs. consensus agreement); or
- Who is responsible for maintaining the meeting minutes following committee approval.

Management Response: Implemented.

The COIP has implemented a standard operating procedure for the Institutional Review Committee that defines the powers of the committee chairs, procedures for voting, who is responsible for monitoring committee membership and maintaining meeting minutes, and whether retired/emeritus UA employees qualify to be members of the committee. The procedures were reviewed at the September 2018 IRC meeting.

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3. Policy education and outreach could be improved.

Condition: The COIP staff regularly meet with departments, project staff, and campus organizations to present information about *ICOIR*. However, we noted the following about the education and outreach:

1. The COIP does not include specific information about the requirements for research administrators to disclose outside interests under *ICOIR*.
2. Information is not geared to researchers whose funding does not flow through SPCS; for example, in cases where research is department funded or comes from an alternate funding source that does not require SPCS approval.

Criteria:

1. Policy Res-101 *Individual Conflict of Interest in Research* defines research administrator as "any individual employed by the University on a full-time or part-time basis whose responsibilities include participation in any manner in contracts or services related to research administration, research contracting, research compliance, responsible conduct of research, sponsored projects services, or technology transfer (whether at the University, college, department, or program level) and who are in a position to influence decisions or commit University resources in the performance of his/her Institutional Responsibilities."

In this policy, Section B. *Requirements for Research Administrators* provides specific obligations for the Research Administrators, including that they "disclose all Outside interests (i.e., theirs and those of their Family Members and Relatives) that can reasonably be deemed Related to their Institutional Responsibilities by submitting a Disclosure to their immediate supervisor, on a form to be provided by the COI Office, with a copy to the head of the Research Administrator's primary department or unit."

2. Policy Res-101 *Individual Conflict of Interest in Research* defines Research as "any organized program of scientific inquiry that involves a systematic investigation designed to develop or contribute to generalizable knowledge that is performed at or under the auspices of the University, whether or not such Research is sponsor-funded."

Causes:

1. The COIP believes that any potential conflicts for research administrators fall under Purchasing Policies Manual 1.4 *Conflict of Interest in Purchasing* and that no further outreach is needed related to the *ICOIR* policy.

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2. The COIP believes that the most risk lies in federally-funded projects and that most researchers with non-federally funded projects would also have federally-funded ones and, therefore, are already aware of the policy requirements.

Effect: Potential for noncompliance with policy, as employees who are required to complete training and disclosure under the policy are not notified or aware of the requirement.

Recommendations:

1. Work with OGC to determine whether Research Administrators must disclose under *ICOIR* or whether other policy disclosures are adequate.

If disclosure under *ICOIR* is determined to be necessary, review *ICOIR* and identify ways that COIP can educate Research Administrators of their disclosure responsibilities and encourage them to comply. This may include:

- Identifying departments whose employees are most likely to fall under the Research Administrator definition and determining which employees "are in a position to influence decisions or commit University resources."
 - Identifying job titles within colleges that may fall under the Research Administrator definition and working with deans and colleges to determine who should disclose under the policy.
 - Updating training materials or creating new materials that specifically address Research Administrators.
2. Update educational materials and presentations to include information about non-sponsored research and the need for those investigators to disclose under *ICOIR*.

Management Response:

1. Target Implementation Date: December 2019.

COIP is evaluating *ICOIR* with an eye toward revising this policy. As part of the process, COIP is seeking guidance from faculty governance, University stakeholders, including OGC. COIP anticipates making policy recommendations by September 2019 with a target date for approval and implementation of December 2019.

2. Implemented.

COIP worked with Human Resources to add a COI disclosure notification to the offer letter templates used during the employee onboarding process for individuals who will conduct any type of research. In addition, an annual campus-wide reminder was sent on June 1, 2018, notifying the campus community of the policy and the requirements for anyone participating in research.