

Institutional Conflict of Interest Policy

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Submitted to:

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Summary

Our audit of compliance with Policy Res-102 *Institutional Conflict of Interest (ICOI)* 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-101 *Individual Conflict of Interest in Research* that will be issued as a separate report.

Background: UA's *ICOI* policy became effective January 6, 2015. According to the Purpose and Summary section of the policy, the goal "is to protect the credibility and integrity of the University, through the identification, review, and management of actual or potential Institutional Conflict of Interest. Left unaddressed, Institutional Conflict of Interest could undermine public trust and support of the University and its Missions." The section also notes that particular attention is to be given to "those circumstances in which Institutional Conflict of Interest may affect, or appear to affect, the safety or welfare of human research participants."

The Definitions section of the policy identifies the following two types of potential conflicts, collectively referred to as Institutional Financial Interests, that are to be managed:

- Significant Financial Interests of a University Administrator: The policy includes a specific definition that describes financial interests such as intellectual property rights or interests that provide income, remunerations over \$5,000 from an external entity, ownership interest in a non-publicly traded entity, and a fiduciary role in an external entity. The policy also includes such interests of University Administrators' family and relatives.
- Significant Financial Interests of the University: The policy definition includes equity or similar interests in an external entity, substantial gifts from an actual or potential commercial sponsor of research, and intellectual property ownership or interests related to an investigational product that is the subject of University research.

ICOI Definitions, Paragraph Q, defines University Administrator as "any individual in a position of administrative leadership of a recognized University college, academic department, business, or other administrative unit, where a regular job requirement is to make institutional decisions on behalf of the University of Arizona."

The policy then describes the responsibilities of University Administrators to report the institutional financial interests to the Conflict of Interest Program (COIP) for review by the Executive Review Committee (ERC).¹ COIP administers *ICOI* and includes a Conflict of

¹ Per *ICOI*, the ERC includes a representative from Internal Audit as one of seven members of the committee.

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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 ERC, and administration of management plans. COIP falls under UA's Office for Research, Discovery and Innovation, led by the Senior Vice President for Research.²

COIP directs University Administrators to the COIP information system to complete conflict of interest training.³ Following training completion, they are automatically granted access to the COIP information system to input any financial interests.

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

Audit Objective: Our primary audit objective was to determine whether adequate controls were in place to ensure compliance with *ICOI*.

Scope: Our scope included internal controls in place between April and October 2017. For certain controls, we sampled transactions that occurred during FY 2017.

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 from UA's Research Gateway website regarding the COIP.
- Reviewing COIP presentation documents, informational brochures, and other methods COIP uses to educate campus administrators about the *ICOI* policy.
- Reviewing the training document and disclosure information provided to University Administrators.
- Discussing procedures with COIP staff to identify the existing internal controls to ensure all University Administrators covered by *ICOI* are in compliance.
- Selecting, via blind pencil stab, one of three FY 2017 ERC meetings and reviewing meeting materials and committee documentation to ensure ERC actions were voted on by the full committee and that committee recommendations were documented in meeting minutes.

² Subsequent to completion of fieldwork, the structure changed and the area is now led by the Interim Vice President for Research.

³ 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 with COIP staff their methods for communicating with the Institutional Review Board (IRB) to ensure conflicts that relate to human subjects research are monitored in accordance with *ICOI* policy and then reviewing ERC meeting minutes to confirm this communication is in place.
- Discussing with the Conflict of Interest Officer COIP information system access provisioning procedures for COIP staff and other administrative units that require access.
- 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 identify the system development process, understand how business rules are initiated and modified in the system, and determine back-up and maintenance controls.
- Discussing the policy with the Office of General Counsel.

Conclusion: Overall, we found that there are not adequate controls in place to ensure compliance with *ICOI*. Contradictory policy verbiage and limited outreach to University Administrators mean that the risks of noncompliance have not been adequately mitigated.

Although overall controls were not adequate, we did identify controls in place to promote compliance with certain parts of *ICOI*.

- COIP has developed procedures to review the disclosures for referral to the ERC and monitor resulting management plans.
- Practices exist to ensure that any disclosed significant financial interests that relate to human subjects research are closely monitored in conjunction with the Human Subjects Protection Program (HSPP). ERC meetings typically include HSPP staff and the IRB co-chairs in an advisory capacity. In addition, COIP offices are in the same building as HSPP which further facilitates close communication.
- There were reasonable controls to ensure the COIP information 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 Quali Research as part of the UAccess Research system.

Detailed findings and recommendations are discussed beginning on page 6. 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 *ICOI* policy compliance 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. | Opportunity for Improvement | 1, 2 | 6, 8 |
| Reliability and Integrity of Financial and Operational Information | Not Applicable | | |
| Effectiveness and Efficiency of Operations | | | |
| <ul style="list-style-type: none"> Conflict of Interest Program information systems are protected and functioning. | Reasonable to Strong Controls in Place | | |
| <ul style="list-style-type: none"> There is reasonable collaboration between COIP and the HSPP to promote safe and effective research when a conflict may be involved. | Reasonable to Strong Controls in Place | | |
| <ul style="list-style-type: none"> Practices are communicated to University Administrators to promote compliance. | Opportunity for Improvement | 1, 2 | 6, 8 |
| <ul style="list-style-type: none"> University Administrators' disclosures of personal and University significant financial interests are reviewed and management plans, when necessary, 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 Significant Improvement | 1, 2, 3, 4, 5 | 6, 8, 10, 12, 13 |
| <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 | 3 | 10 |
| <ul style="list-style-type: none"> Actions of the Executive Review Committee are in compliance with policy. | Opportunity for Improvement | 5 | 13 |

We appreciate the assistance of UA employees during this audit.

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Audit Results, Recommendations, and Responses

1. The policy contains statements that contradict other portions of the policy.

Condition: The *ICOI* policy contains conflicting language that makes it unclear whether all University Administrators or only those in research areas are covered by the policy. COIP interprets the policy to only apply to those in research, but during the audit we determined that the original intent of the policy was to apply to all University Administrators.

Criteria: Policy Res-102 *Institutional Conflict of Interest* includes a definition of University Administrators as follows:

“Any individual in a position of administrative leadership of a recognized University college, academic department, business, or other administrative unit, where a regular job requirement is to make institutional decisions on behalf of the University of Arizona.”

However, the Purpose and Summary section states, “This Policy is managed by the Conflict of Interest Program, a unit of Research Compliance Services, and applies to those University Administrators who have authority over the Conduct of Research, as well as to University Administrators with decision-making authority in the University’s research administration and Tech Transfer Arrangements.”

Cause: At some point after the *ICOI* policy was developed by the committee, and before it became effective, a statement was added to the Purpose and Summary section that states that the policy applies to research administrators only. However, the policy definition of “University Administrator” was not revised to clarify to whom the policy applies.

Effect: Until it is clear whether University Administrators who are not involved in research should be disclosing their significant financial interests, public trust of the University and its missions may be at risk.

Recommendations:

1. Work with the Office of General Counsel (OGC) to evaluate whether the policy needs to be updated or clarified.
2. Develop a process to educate University Administrators of their responsibilities under the revised policy.

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Management Response:

1. Target Implementation Date: December 2019.

COIP will work with the Interim Vice President for Research and OGC to evaluate who the policy applies to and will recommend revisions to the policy as needed.

2. Implemented.

COIP has implemented COI training specifically geared toward UA Administrators and began offering it in March 2018. An annual campus-wide reminder was sent on June 1, 2018, notifying the campus community of the policy and directing them to the COIP website for additional information. Additionally, COIP worked with Human Resources to add a COI disclosure notification to the offer letter templates used during the employee onboarding process for University Administrators.

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2. Outreach and training are not provided regarding institutional financial interests.

Condition: COIP does not have a process to train University Administrators on their responsibilities to report institutional financial interests, either through COIP presentations or the Conflict of Interest website.

Criteria: Policy Res-102 *Institutional Conflict of Interest in Research*, Paragraph A.4.b, states that "All University Administrators are responsible for disclosing Significant Financial Interests of the University of which they become aware, and will affirm that this disclosure obligation has been fulfilled by completion of certification to the Conflict of Interest Program."

Cause: COIP's interpretation of policy Res-102 is that it only applies to administrators in the Research area and, thus, all outreach focuses on educating employees about Res-101 without considering additional requirements of Res-102.

Effect:

- Noncompliance with the policy requirements.
- University Administrators may not be aware that they have a responsibility to disclose institutional financial interests to COIP.
- COIP and the ERC may not be notified of all University Significant Financial Interests.

Recommendations:

1. Develop an outreach and education plan to alert University Administrators to their responsibilities to report Significant Financial Interests of the University. The plan should include identifying job titles/departments that meet the definition of University Administrator and targeting the communication to the identified administrators. The plan should also consider outreach specifically to newly appointed University Administrators.
2. Develop a process to require University Administrators to affirm that they have fulfilled the obligation to disclose University Significant Financial Interests. When developing the process, consider whether requiring annual certifications from all University Administrators, whether they have anything to disclose or not, would facilitate the annual compliance monitoring required by another section of the policy.

Institutional Conflict of Interest Policy

Management Response:

1. Implemented.

COIP has implemented COI training specifically geared toward UA Administrators and began offering it in March 2018. Additionally, COIP worked with Human Resources to add a COI disclosure notification to the offer letter templates used during the employee onboarding process for University Administrators.

Additionally, in June 2018, COIP, in conjunction with PACS, issued a campus-wide reminder of University Administrator's COI obligations which stated:

If you have a position of administrative leadership (e.g. Director, Head, Dean, *etc.*), you are required to comply with the University's Institutional Conflict of Interest Policy. In particular, you must disclose your Significant Financial Interests at the time of your appointment, annually thereafter, when you acquire a new Significant Financial Interest, and when you become aware of additional Significant Financial Interests of the University.

The Conflict of Interest disclosure system can be accessed here: <https://uavpr.arizona.edu/COI>. For more information about the University's COI requirements, please review the above-linked policy and visit the COI Program's Website on the University's Research Gateway. If you have any questions, please reach out to us at coi@email.arizona.edu or by phone at 520-626-6406.

The campus-wide reminder will be sent annually.

2. Target Implementation Date: December 2019.

Through an annual campus-wide reminder, COIP has instructed individuals who have a position of administrative leadership to disclose their Significant Financial Interests at the time of their appointment, annually thereafter, when they acquire a new Significant Financial Interest, and when they become aware of additional Significant Financial Interests of the University. COIP has instructed University Administrators to make this disclosure in the COI disclosure system. Each June, University Administrators who have previously submitted a disclosure receive emails every 7 – 10 days reminding them to submit their annual certification.

RDI is working with UA Information Technology to implement the Kualu COI module which will integrate COI with the IRB and Awards modules. The new proposed module will include questions related to University Administrators' disclosure requirements under this policy. We hope to enter into an agreement with Kualu to begin programming in Fall 2018. The implementation timetable is contingent on resources. The Kualu module will provide annual certifications from University Administrators.

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3. Record retention procedures are not documented or approved.

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

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

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

Criteria:

- Policy Res-102 *Institutional Conflict of Interest*, Paragraph C, states, "The Conflict of Interest Program will maintain all disclosures made, all Executive Review Committee reviews, determinations, recommendation, and all management plans for a period of six (6) years following elimination of the Institutional Financial Interest or the completion of all related University research, whichever is later."
- UA's Records Management and Archives (RMAA) website states that UA subscribes to the Arizona Revised Statutes 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 the procedures be documented to increase compliance and ensure consistency when there is department turnover.

Cause: COIP believed they were following UA records management policies, but had not evaluated how their records would be stored or specifically what category their records fall under to determine the retention period.

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Effect:

- Noncompliance with *ICOI* policy.
- Procedures may not be in compliance with A.R.S. or UA policy.
- Documents may not be maintained in a readable manner or may be inadvertently deleted prior to the end of the retention period.
- Records in a system may not remain accessible if a new system is implemented and the prior system becomes outdated.

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. Write 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 OGC to discuss the COI Program'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 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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4. Required annual monitoring is not performed.

Condition: COIP does not have a process in place to conduct required annual compliance reviews of the University community's compliance with *ICOI*.

Criteria: Policy Res-102 *Institutional Conflict of Interest*, Paragraph E.1, states, "The Conflict of Interest Program will conduct annual reviews of the University community's compliance with this policy. Such reviews will include, at a minimum, random selection of University departments and University Administrator(s) to conduct a review of disclosures and random selection of submitted disclosures to ensure accuracy."

Cause: COIP feels they are still early in the implementation process for this policy and have not yet had time to develop the annual review process.

Effect: Noncompliance with the policy requirements.

Recommendation: Develop and implement annual reviews in compliance with the policy. Ensure that records of the reviews are maintained as evidence of compliance.

Management Response: Target Implementation Date: December 2019.

Beginning in Fall 2018, COIP will be periodically monitoring compliance with this policy. The monitoring plan is currently being developed. RDI is working with UITS to implement the Kualii COI module which will integrate COI with the IRB and Awards modules. The new proposed module will include questions related to University Administrator's disclosure requirements under this policy. We hope to enter into an agreement with Kualii to begin programming in Fall 2018. The implementation timetable is contingent on resources. The Kualii module will provide annual certifications from University Administrators. Upon implementation, COIP will develop an annual review process that is compatible with the Kualii module.

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5. The ERC does not have an approved, written charter.

Condition: The ERC is integral to UA's ability to comply with its *ICOI* 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;
- 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.

Cause: The ERC and the Conflict of Interest Officer have established practices to ensure the ERC worked efficiently but, due to the workload, the procedures had never been written or formally approved by the ERC.

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 *ICOI*.
- Voting procedures and meeting minutes may not be consistent.

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

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

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Management Response: Target Implementation Date: December 2018.

COIP has completed a draft standard operating procedure for the Executive Review Committee that defines the powers of the Executive Review Committee chairs, voting procedures and who is responsible for monitoring committee membership and maintaining meeting minutes.