

University of Colorado Boulder

Research & Innovation Office

Office of Research Integrity

Academic & Researcher Conflicts of Interest and Commitment Policy

Procedures and Guidelines

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I. Introduction

This procedures and guidelines manual is intended to assist the University of Colorado Boulder's Conflicts of Interest and Commitment (COIC) Office Personnel and COIC Committee Members in administering the university's Academic and Researcher Conflicts of Interest and Commitment Policy and Standards (COIC policy).

The centerpiece of CU Boulder's COIC policy is the disclosure of significant personal and financial interests. Transparency is integral to gaining public trust that academic and researcher decisions and actions are made without the undue influence of personal benefit. Disclosure also meets the requirements of federal grant sponsors that the campus have a robust conflict of interest policy. The primary purpose of this is to ensure that the integrity of research and scholarly activity, performance of university responsibilities, academic progress of students, and protection of human subjects are not affected by the outside financial and personal interests of a CU Boulder faculty member or researcher. Additional university objectives include protecting intellectual property; avoiding misuse of procurement/purchasing privileges and the utilization of university space; and mitigating conflicts related to time and effort of employees regarding their university responsibilities.

II. Disclosure

All academic and research personnel must submit an annual disclosure of significant interests related to their university responsibilities. It is the role of the COIC Office to conduct a judicious review of whether information disclosed indicates an actual, perceived, or potential conflict of interest or commitment. Disclosers must not withhold disclosing significant interests in the belief that no such conflicts exist.

III. Disclosure Review

The primary purpose of a disclosure review is to determine whether a significant interest exists that could bias the conduct of work at CU Boulder. Significant interest is defined in the COIC policy as a financial or other personal interest received from or held in an entity outside of the university that reasonably appears to be related to the Discloser's Institutional Responsibilities and that exceeds certain thresholds. A significant interest can create an actual, perceived, or potential conflict of interest.

A disclosure review is also conducted to determine if a conflict of commitment exists. All external activity that meets disclosure guidelines must be disclosed. Employees with faculty appointments have a primary responsibility to the University and may not engage in any endeavors that adversely affect the discharge of their university duties. The One-Sixth Rule limits the total consulting activity of tenured and tenure-track faculty to 19.5 days per semester (39 days during the academic year). The One-Sixth Rule process is part of a CU System policy and "housed" within Faculty Affairs on each of the CU campuses. The One-Sixth Rule does not apply to employees without faculty titles; they must also receive approval for outside work but may not use university time for it.

Disclosures are made via the online InfoEd reporting system. They are first automatically screened for significant interests. If none are reported, the review ends there; no COIC Personnel review the disclosure. If one or more significant interests is reported, then the disclosure is routed to the COIC Office for review.

IV. Review of Academic and Researcher Disclosures

The purpose of a disclosure review is to:

- Identify actual, potential, or perceived conflicts of interest or commitment
- Assess the potential for adverse effects of an identified conflict
- Determine how to address the conflict

A. Risk Analysis

At issue is whether a disclosed significant interest could compromise or appear to compromise the discloser's judgment in exercising his/her institutional responsibilities. There are two areas of risk that require evaluation:

- the discloser's university activities
- his/her association with the external entity in question

The following questions are useful in determining the degree of risk. The greater the number of affirmative responses, the greater the concern.

- What is the discloser's role/job title (e.g., Full professor, research associate, research assistant, non CU employed student, etc.)?
- Is the discloser affiliated with an external entity and, if so, does that relationship meet one or more of the disclosure criteria that necessitates further review?
- Is an external entity funding the discloser's research/scholarly activity at the University or elsewhere?
- Does the discloser participate in federally sponsored research and, if so, to what degree does there appear to be overlap between the federally sponsored research activities and the activities associated with the external entity?
- Are students involved in the discloser's University research/scholarly activity or activities associated with the external entity?
- Are human subjects involved in the discloser's University research/scholarly activity or activities associated with the external entity?
- Is IP involved in the discloser's research/scholarly activity and to what degree is it at risk regarding the discloser's external affiliation(s)? (Has the campus' Consulting Addendum been put into effect with the external entity?)
- Does the affiliation involve a foreign entity? If so, OEC must also review the disclosure as does OCG if the discloser has a federal grant.
- Does the discloser or other CU Boulder employee make purchases from the external entity?

- Does the external entity arrangement involve the utilization of university space or equipment?
- What percentage is the discloser employed at the University? Are there any concerns about the time spent on activities related to the external entities? (Is a One-Sixth approval form in place with the academic department or have other arrangements such as an appointment reduction been made?)

There are five steps to assessing the degree of risk associated with a significant interest:

1. Determination of whether there is a significant interest (SI) as defined in the COIC Policy. This is generally the responsibility of the COIC Director, although the COIC Committee may influence that decision during a review.

SIs are first determined by looking at the established thresholds. Examples of SI include outside remuneration > \$5,000, the sum of income from and equity in a publicly traded entity valued at >\$5,000, or equity in any amount from a non-public entity. Ownership interests > 5%, no matter the value, are considered to create an SI. In general, the greater the value of the interest, the higher the risk. Stock options are less clear, though generally they are considered to create an interest in the well-being of the company that could affect the discloser's judgment.

Membership on a Scientific or other Advisory Board absent a corresponding financial interest most likely does not create an SI unless the board has some say in how company resources might be distributed to the discloser's institution or over how research can be conducted.

However, if there is an appearance of direct overlap with projects conducted at the University, a conflict is more likely to exist.

Travel reimbursement or sponsored travel related to institutional responsibilities to a U.S. destination valued >\$2500 per entity in the 12-month period preceding disclosure or to a foreign destination in any amount must be reported as SI. Exclusions from this requirement include travel that is reimbursed or sponsored by the University of Colorado; a federal, state, or local government agency; another institution of higher education; an academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education in the U.S.

Research collaborations with an entity other than a U.S. institution of higher education from which monetary or non-monetary compensation is received can constitute an SI. Collaborations with commercial entities pose the greatest risk of a conflict. This is especially true if the discloser is an owner or otherwise affiliated with the entity. Sponsored research agreements in which a discloser participates and that involve an entity in which the discloser has an interest are of special concern.

Holding a position with influence over decisions in an outside entity is a SI regardless of ownership stake or amount of remuneration. These include, but are not limited to, executive roles (CEO, COO, CTO) and board membership. Consulting relationships can be SIs if they meet the financial threshold and are related to the discloser's university responsibilities.

2. Determination of the degree of overlap of the interests of the entity in which the significant interest is held with the work of the discloser at CU. This is generally the

responsibility of the COIC Director although the COIC Committee may influence that decision during a review.

Sometimes an overlap is clear from the information presented in the disclosure. Other sources of information include but are not limited to the list of current awards and proposals maintained by the Office of Contracts and Grants; the faculty member's CV and/or research interests as described in her/his university web page; and/or the entity's web page (if there is one). More commonly, additional information must be elicited from the discloser with a standardized set of disclosure follow-up questions available on the shared server. Members of the COIC Committee may be able to provide some personnel information and often provide content area expertise.

For consulting, the relevant aspects to look at are the business of the entity to which the consulting service is delivered and the activities and deliverables associated with that service. Other factors to consider are whether the discloser is an owner of the entity; whether the entity does business with the university, including funding the discloser's research; whether students are involved with the entity; and whether the entity is a business or a non-profit.

3. Determination of the scope of the relationship between the discloser and the outside entity.

Affiliations with outside entities range from a simple ownership interest to board membership to holding an executive role (e.g., CEO or CTO). Here key factors include job title, if any, responsibilities, and days spent working for the entity. In some cases, disclosers have reduced their appointment at CU to spend a larger percentage of their time with the entity than is permitted under the One-Sixth Rule. In general, the greater the breadth of the obligation to the entity, the higher the risk of a conflict.

4. Determination of whether the significant interest could directly and significantly affect the research process or outcomes (i.e., design, conduct, and reporting).

Direct effect includes, but is not limited to, situations in which the research results would be plainly relevant to the development, manufacturing, or improvement of products or services of an external entity. Significant effect includes, but is not limited to, situations in which the research results would materially impact the external entity's earnings or sales. The more similar the business of the entity is with the Discloser's research, the greater the risk of a conflict.

The COIC Committee chair should be consulted when situations present ambiguities or complexities regarding the relationship between the significant interest and the discloser's research. At the chair's request, other Committee members may also be consulted in their areas of expertise.

5. Determination of whether the combination of significant interest and relationship of business to university responsibilities creates a conflict of interest that must be managed. This is generally the responsibility of the COIC Director, although the COIC Committee may influence that decision during a review.

Generally speaking, if there is a significant interest and a non-trivial overlap between the discloser's university responsibilities and the entity's business, there is a potential conflict of interest. Other factors are whether the entity does business with the university, whether students are involved with the entity, and whether human subjects are involved. Where these exist, the likelihood of a conflict is greater and so the situation should be managed.

The COIC Committee chair, or the Committee, should be consulted if there is uncertainty about the degree of overlap or the level of risk it presents. It is better to be conservative and implement a management plan in most situations where the potential for undue influence exists. Even if that potential is *de minimus*, the perception of a conflict must still be considered.

B. Review Status Designations:

At the beginning of the calendar year, all disclosers have the status "Pending Submission" that remains until they submit a disclosure. Once the COIC Office completes its review, one of the following status designations is selected. The first eight are the most commonly assigned to disclosure submissions.

1. In Progress:

The Discloser has begun to enter information but has not yet completed the disclosure for final submission. At this point, the disclosure does not meet the federal requirement that a disclosure be on file prior to grant/contract submission and disbursement of funding associated with federally funded award monies. Each month disclosers in this status receive an e-mail asking them to certify and submit their disclosure.

2. No Conflict Reported:

Upon initial submission, the Discloser has answered "no" to all the screening questions. The disclosure meets the federal requirements that a disclosure be on file prior to submission of a grant/contract and that conflicts be identified and managed.

3. Pending Review:

The Discloser answered "yes" to one or more of the screening questions. The disclosure must be reviewed by COIC personnel. In this status, the disclosure meets the federal requirement that a disclosure be on file prior to submission of a grant/contract but does not meet the requirement that any conflict identified be resolved. Thus, awards and/or contracts cannot move forward, e.g., funding disbursed, procurement requests approved, IRB approval obtained, etc.

4. Reviewed No Conflict:

The Discloser answered "yes" to one or more of the screening questions, and the disclosure underwent a review resulting in the determination that there is no conflict. The disclosure meets the federal requirements that a disclosure be on file prior to submission of a grant/contract and that conflicts be identified and managed.

5. Under Review

One or more of the answers to the screening questions were affirmative. The disclosure is in the process of review and/or approval. In this status, the disclosure meets the federal requirement that a disclosure be on file prior to submission of a grant/contract but does not necessarily meet the requirement that any conflict identified be resolved. Awards and contracts cannot move forward (e.g., funding disbursed, procurement requests approved, IRB approval obtained, etc.) without resolution of the disclosure or at the COIC Director's discretion. For example, if most of the approval process for a Management Plan has occurred, the COIC Director may determine that the awards, contracts, and approvals can go forward. In rare cases, such as when a new disclosure leads to an assessment that an existing conflict that had been under a Management Plan is now not sufficiently managed, the COIC Director has the discretion to determine that proposals may not be submitted until an updated Management Plan is in place.

6. Pending Monitor Report:

The Discloser submitted a disclosure and was sent an automated response acknowledging that submission and states that the follow-up annual monitoring form is due before a review can be completed. In this state, the disclosure meets the federal requirement that a disclosure be on file prior to submission of a grant/contract but does not meet the requirement that any conflict identified be resolved. Thus, awards and/or contracts cannot move forward, e.g., funding disbursed, procurement requests approved, IRB approval obtained, etc.

7. Reviewed Conflict Managed with Monitoring:

The Discloser has a current Management Plan in place and has submitted an annual monitoring report, which is due in conjunction with the annual disclosure submission. This designation is only selected once the Management Plan has been updated if necessary due to a meaningful change in the Discloser's status. The disclosure meets the federal requirements that a disclosure be on file prior to submission of a grant/contract and that conflicts be identified and managed.

8. Reviewed Conflict Managed, Consulting Only re: 1/6th Rule:

This designation clarifies that consulting is being done consistent with the One-Sixth Rule but does not involve ownership of the external entity to which the consulting service is provided. The disclosure meets the federal requirements that a disclosure be on file prior to submission of a grant/contract and that conflicts be identified and managed.

9. Reviewed Conflict Managed – Management Plan on Hiatus

This designation is used when a management plan appears to no longer be currently relevant because the conflict no longer exists but has the potential of returning in the future. This status may be assigned each year, indefinitely, but more likely only for two years at which point it can be determined whether the plan is obsolete or needs to be reactivated. The disclosure meets the federal requirements that a disclosure be on file prior to submission of a grant/contract and that conflicts be identified and managed.

10. Reviewed No Conflict – Entity Ownership:

This designation is used when a Discloser is affiliated with an external entity that initially appears to have a potential conflict but, upon further review, no conflict exists. It acknowledges the existence of the external entity, but that the superficial appearance of a conflict does not warrant management. Note, if the nature of the affiliation changes, a new review with subsequent Management Plan might be necessary.

11. Reviewed Conflict Managed – Directed to Recuse

This status is reserved for non-researcher types of positions that involve oversight of administrative processes pertaining to research/researchers. For these individuals involved with external entities where there is the appearance of or potential for a conflict of interest, the individual is directed to obtain supervisor approval and to follow the University of Colorado Boulder campus guidelines for recusal.

12. Unresolved Conflict

Describes situations that remain unresolved at the end of the calendar year. This is typically due to failure to submit an annual monitoring report or to an outstanding and not yet finalized Management Plan. Review comments should be added in InfoEd to explain the reason for this designation. Disclosers are not in compliance with the COIC Policy. Note that this status is reset at the start of the new year, so a separate record of disclosures in this status should be created before that time.

V. Managing Academic and Researcher Conflicts of Interest and Commitment

A. COIC Management Plan

When the COIC Director determines that a conflict requires management, a Management Plan is implemented. Plans are based on a standard template consisting of three sections: 1) a situation description; 2) a set of commitments aimed at mitigating the conflict; 3) notification of monitoring. Supplemental provisions may be added to the basic template as needed (e.g., from OEC, CCO, Venture Partners, or funding agencies such as the Department of Energy/ ARPA-E).

The situation description typically includes the following:

1. University status of discloser
2. Relationship to entity (role, ownership, duties)
3. Entity description
4. Similarities/ differences with research and university responsibilities
5. If NIH grant recipient: disclaimers if applicable
6. Ties to university
7. Involvement of other university employees
8. Student involvement
9. Human subject involvement
10. Source of grant funding

The COIC director drafts the plan and sends it to the discloser for review. He/she is asked to make edits and additions to the situation description for accuracy and completeness and to indicate the chosen commitment options. Subsequent revisions are made as necessary until a final document is achieved. Once the document is finalized, it is circulated via DocuSign for signatures from the discloser, Supervising Authority (typically a department chair or Director), and Dean. When complete, copies of the signed plan are placed in the disclosure's shared server folder and in InfoEd and are sent to the discloser and his/her academic unit.

B. Monitoring

At the time of annual disclosure, disclosers with a previous status of Conflict Managed with Monitoring are required to submit an annual monitoring report. The list of current Management Plans should also be consulted to catch any disclosers who have had a new Management Plan implemented since their last disclosure. The COIC Office e-mails a reminder that includes the report form as an attachment. A monitoring report is due only once per year, unless an additional report is requested by the COIC Office.

The COIC Office will conduct an annual review of at least a 10% random sample of active Management Plans for the purpose of monitoring compliance with the disclosure provisions according to the following procedure:

1. Select at least 10% of the current Management Plans at random for review.
2. Notify Disclosers whose Management Plans have been selected for review via e-mail.
3. Check public sources to identify the publications and/or presentations attributed to Discloser and related to their conflict in the preceding twelve (12) months.
4. Verify disclosure of the conflict addressed in the Management Plan by requesting of Discloser (a) a copy of the disclosure presentation slide, and/or a copy of the publication with disclosure, or a sample thereof, and (b) copies of conflict notifications to subordinates and students.
5. Notify the Discloser's Supervising Authority if a response is not received within a reasonable period.
6. Report monitoring results to the Assistant Vice Chancellor for Research Integrity and Compliance, the Discloser's Supervising Authority, and the Discloser.

The COIC Director will determine whether appropriate disclosures were made by considering the relationship between the conflict and the subject of the research and may seek guidance from a subject-matter expert in making that determination. In the absence of the appropriate disclosure, the Director will inform the Discloser and the Supervising Authority of that determination and provide specific instances of failure to disclose. The purpose is to educate about the importance of the obligation to disclose. At a minimum, the COIC Office will require the Discloser to take compliance action as necessary such as notifying journals of the failure to disclose the Conflict. In addition, the Discloser's Management Plan will be selected for audit the subsequent year.

C. Terminating Management Plans

At times, the need for a current Management Plan may cease to exist. After reviewing a disclosure, annual monitoring report, and Management Plan, the COIC Director may make that assessment due to a change in circumstance. This most likely is because the affiliation the plan addresses has ended and with it the conflict. It may also be that the nature of the affiliation has changed in a way that removes the risk that it will directly and significantly influence the design, conduct, or reporting of the discloser's research or the performance of his/her institutional responsibilities. In such cases, the COIC Director will review and confirm the status of the affiliation with the discloser and make a final determination about whether to terminate the Management Plan. The termination will be made in writing, including a brief explanation of why the conflict no longer exists. The termination document is circulated via DocuSign for signatures from the COIC Director, Discloser, Supervising Authority, and Dean. Once signed, a copy of the document is placed in the discloser's shared server folder and in InfoEd.

D. Unmanageable Conflicts

For those situations where other management strategies are believed to be insufficient, the following options may apply:

1. Elimination of the cause of the conflict, e.g., divestiture of equity, change in academic appointment, termination of employment, etc.
2. Elimination of the discloser from the affected research, partially or totally (e.g., if human subjects, the conflicted individual is not allowed to recruit or consent subjects; the investigator removed him/her from the project; not allow a proposal to move forward in OCG; not allow procurement to occur, etc.)

The COIC Committee should advise on this determination, and subsequently the COIC Director should discuss the matter with the department Chair/Director before recommending a course of action to them. The Supervising Authority makes the final decision about the action to be taken.

VI. Conflicts of Interest and Commitment Involving Students

Based on the principle that a student's academic progress shall not be compromised, appear to be compromised or have the potential of being compromised by any external affiliation related to faculty/advisors/ graders, a section within the Management Plan template addresses student and subordinate protections.

All graduate students and any undergraduate (typically working on honors theses or on IRB projects) are required to disclose if they are engaged in the design, conduct or reporting of research, or if they are involved in a CU Boulder employee-affiliated company/entity. During the 2018-2019 academic year, the COIC Committee determined:

- Students who are also CU employees will be reviewed on a case-by-case basis using the same criteria and similar guidelines as regular CU employees. Management Plans may be put into effect for students.
- Non-CU employed students who own/co-own a company, hold a leadership or advisory position in an external entity, or are affiliated with a CU employee-affiliated company are likely to require a Management Plan depending on the nature of the engagement with the external entity.
- Legal Counsel for OCG Contracts confirms that students who are not CU employees and who are employed by an external entity do not necessarily require any contractual agreement with CU, including a Management Plan and that they own their own intellectual property. Barring any other concerns, these students should receive an approved status of: Reviewed, No Conflict and their approval letters should include standard cautionary language about the risks related to potential delays in publications that could influence their academic progress or time to degree completion.

VII. Conflicts of Interest and Commitment and the Creative Arts

Not all concepts and conventions pertaining to federal regulations governing academic and researcher conflicts of interest translate easily to practices associated with the creative arts. However, using the National Endowment of the Arts (NEA) as an example, adherence to federal regulations (2CFR 200.122, 200. 318) applies to NEA grants and cooperative agreements. The COIC Committee should have at least one faculty representative from the creative arts to assist in reviews and decisions for situations that do not readily lend themselves to the business processes established for other academic fields.

VIII. Outside Employment

Not all consulting and outside employment require a Management Plan. Regardless of whether it does, university employees in academic and research positions are responsible for:

1. including the [Standard Addendum for Consulting and Third Party Employment](#) into external agreements in order to avoid conflict with the University's Intellectual Property policy
2. providing updated disclosure reports
3. obtaining department approval via the [Consulting Approval Form](#) (1/6th Rule)

A Management Plan may be appropriate under the following conditions:

- The work is closely related to on-going research and may directly and significantly affect that research.
- The consulting or other outside work is done for an external entity that does business with the university
- The work is done for an external entity with which CU Boulder students are involved

In general, a Management Plan is not needed in the following situations:

- Consulting or other outside work is only somewhat related or unrelated to on-going research
- The work is for a U.S. state or federal government agency
- The work is for a non-profit whose advocacy is only somewhat related or unrelated to on-going research

IX. Disclosure Reporting Periods and Processes

A. Campuswide Notifications

Although the InfoEd reporting system can accept reports at any time, January 15- March 31 of each year is the primary reporting period at CU Boulder. The second largest period of reporting occurs at the beginning of the fall semester for new employees. In between these standard periods, departments are responsible for directing new employees of COI disclosure requirements to be completed within 30 days of their official start date. During the standard reporting times, administrative emails (jointly from the Provost and VCR's offices) are distributed campuswide. Guidelines for that process are specified in the COIC Policy. For legal and auditing purposes, it is important to archive these emails and to post the latest versions on the COIC website so that such notification can serve as evidence when needed.

B. Rules Re: Proposal Submissions and Award Monies Distribution

During the disclosure reporting periods the COIC Office needs to coordinate with the Office of Contracts and Grants regarding the business processes and conditions pertaining to grant proposal submissions and award monies distribution. The following is a template for the email notification sent to OCG-All Staff in mid-December:

Key Dates

[period of InfoEd updates and maintenance] – InfoEd is view-only and the DEPA system is not available for submissions. Manual DEPA forms must be completed and sent to coi@colorado.edu.

[return from Winter break] – The InfoEd DEPA reporting system will be open and ready for submissions with an updated DEPA form that includes new fields for disclosing foreign activities and interests.

[two working days prior to beginning of disclosure period] – An E-memo will be sent to campus from the Provost's office regarding the annual disclosure period, with instructions on how to access the InfoEd DEPA system.

January 15 [current year] – The [current year] DEPA primary reporting period begins and runs through March 31. Note that DEPA Forms – and updates within thirty (30) days of a change in status – can be submitted at any time throughout the year.

Updated Business Rules – Changes to Proposal Submissions and Awards

The *updated* business rules regarding conflicts of interest and commitment reporting via the InfoEd DEPA Form submissions are as follows:

January 1 – February 14, [current year]:

- Having a current DEPA in submitted status (within one year of the date of the proposal submission date) on file will meet the DEPA requirement for proposal submission.
- Award monies will not be released unless either the PI's DEPA has been reviewed with no conflict within the last 12 months of the date of award acceptance or a [current year] DEPA form has been submitted and reviewed or is under review with COIC authorization that money can move forward.

Beginning February 15, [current year]:

- PIs **must have a [current year] disclosure** that at least is in a submitted status before the proposal can be submitted.
- Award monies will be released only if PIs have a [current year] DEPA Form submitted and reviewed or under review with COIC authorization that funding can move forward.

Additional Guidance

- OCG is **not required** to confirm the DEPA status for Co-PIs or other named research personnel. It is the responsibility of PIs to ensure that all personnel involved in the design, conduct or reporting of research have met the DEPA requirements.
- If the last DEPA filed is older than twelve (12) months, then the discloser must submit a [current year] DEPA *before* proposal submission.
- An award or modification can be signed either fully or partially prior to the disclosure being completed, so long as the award action is not moved forward to CCO to be setup in the financial system.
- Awards can be signed and funding released if PIs have a green (Reviewed – No Conflict, or No Conflict Reported) or yellow (Conflict Managed) status icon in the personnel sections.

Reminder Regarding DOE and PHS/NIH Projects

DOE and PHS/NIH projects require the researcher to be current with PHS/NIH training (required every four (4) years). Disclosers must indicate DOE or PHS/NIH funding on the DEPA Form to access the training module, and then check a box on the form indicating their completion.

X. COIC Policy Violations

The COIC disclosure process is based on trust that faculty and researchers will report their significant interests truthfully, accurately, and completely. Nevertheless, the COIC Office may determine that someone has failed to adhere to the disclosure requirements. Allegations of COIC policy violations are pursued through the process outlined in the Professional Rights and Responsibilities of Faculty Members and Roles and Professional Responsibilities of Academic Leaders (PRR). According to that document, it is unacceptable conduct for a faculty member to:

[fail] to disclose the faculty member's significant financial interests (including the significant financial interests of family members), consulting activities, external entities and foreign affiliations, or other potential conflicts of interest in a timely manner, as required by applicable federal regulations and university requirements, and failure to comply with any related management plan; [or]

[fail] to disclose a conflict of interest or failure to remove oneself from situations involving a conflict of interest or the appearance of impropriety in a timely manner

The COIC Director will notify the Supervising Authority after he/she makes a determination that the COIC policy has been violated. The COIC Director will present evidence to substantiate the alleged violation and report on all efforts that had been made to achieve compliance. The COIC Office will assist thereafter with the matter as requested.

XI. Education and Outreach

The COIC Office provides education and outreach to explain the COIC Policy and support the disclosure process.

1. A general COIC training video is required viewing for Disclosers once a year. The video is updated annually to reflect any changes in the COIC Policy or the disclosure process.
2. At times, a department or other unit will ask for a presentation about conflicts of interest and commitment.
3. The Office of Faculty Affairs hosts a New Faculty Orientation every August, at which the COIC Office may provide information.
4. Each Fall, the Faculty Director of the Responsible Conduct of Research Education Program will contact the COIC Office about participation in a session of the RCR course on COI. All NIH supported trainees and any NSF-supported student or postdoctoral fellow must attend the course.

XII. COIC Reports

The COIC Office reports on its activities and on results of the administration of the COIC Policy.

A. COIC Committee

In addition to specific disclosure reviews as needed, the COIC Committee receives periodic reporting regarding the numbers and kinds of disclosures submitted and the status of Management Plans.

B. Annual Report

An annual report is provided to the COIC Committee, Vice Chancellor for Research, the Provost, and the Chancellor's Office. The report should be compiled in January for the previous reporting year. Reports minimally should include:

- totals disclosures and non-disclosures by academic unit
- analysis of COIC Management Plans
- risks and plans for the upcoming reporting period

XIII. Reporting to Federal Sponsors

Routine compliance disclosure information is not typically reported to federal sponsors. However, changes in statuses and implementation of a Management Plan may warrant disclosure to a sponsor interested in a particular Discloser's status. Some sponsors may choose to require specific language be included in a Management Plan. The COIC Office works closely with the Office of Contracts and Grants to ensure compliance and transparency to sponsors regarding conflicts of interest and commitment.

U.S. Public Health Service entities including the National Institutes of Health require notification when a financial conflict of interest (FCOI) that could directly and significantly affect the design, conduct, or reporting of sponsored research is determined to exist for a PHS/NIH-funded researcher or if after conducting a retrospective review the institution has reason to believe that research bias has occurred. When a management plan is implemented for a PHS/NIH-funded researcher, the FCOI analysis must be done to determine whether the situation warrants sponsor notification. If so, a FCOI report must be filed within 60 days of discovering the conflict.

XIV. Colorado Open Records Requests (CORA), Audits, and Inquiries

Most non-student disclosed information is subject to CORA, audits, and inquiries. Release of information to any agency, business, or group outside of the University must be coordinated with campus Legal Counsel. Due to federal protections afforded to university students (via FERPA), care must be taken when reported conflicts of interest and commitment information is released to ensure that information about students (e.g., those named as employees in a faculty company) has been redacted. Information submitted *by* students who are also university employees is also considered protected under FERPA.

XV. Signature Authority

Per federal regulations, an employee at the institution who can assume the Financial Conflicts of Interest Role, “with the authority to initiate, edit, submit, revise, view and delete records and documents” pertaining to FCOI reporting, is to be identified. That person is by default the COIC Director.

This authority process is initiated by the AVR and Director of the Office of Grants and Contracts (referred to in 3.1., above, as SO) and submitted to the Chancellor with notifications to System’s Legal Counsel and other relevant parties.

In addition to the FCOI Role, and on occasion, parties external to the University will ask the COIC Director to formally verify the status of a discloser. Brief letters, memos, notices, and form completions are typically acceptable types of documentation that may be provided. However, the Director does not have the authority to enter into legally binding agreements or other types of legal instruments on behalf of the University, even though they may appear primarily to be for the purposes of verification. For those cases, Legal Counsel should be contacted for further direction.