

CWRU CONFLICT OF INTERESTS MANAGEMENT PLAN GUIDANCE**Introduction**

The purpose of this guidance document is to serve as a resource to faculty, staff, students, and trainees regarding the implementation of conflict of interests management plans developed by Case Western Reserve University (CWRU; University). Not every section in this guidance will apply to you and/or your management plan. The management plans approved by the Conflict of Interests (COI) Committee are specific, directed, and designed to address an individual conflict of interest. Management plans are developed with input from affected individuals.

Disclosure: Publications/Presentations

You are required to accurately disclose your individual and the institutions' financial interest on publications/presentations arising from the conflicted research. The requirement for disclosure does not have an expiration date. All publications/presentations that are developed from the conflicted research, regardless of how much time has passed, would be required to have the appropriate disclosure statement.

For example, when describing the nature of your individual financial interest, depending on the circumstances, the language might read:

This investigator:

- “serves as an officer with [entity/company/organization]” and/or;
- “has an ownership interest in” and/or;
- “receives compensation from” and/or;
- “invented intellectual property being commercialized by an outside entity” or
- “invented intellectual property being used in this research”

For example, when describing the nature of the institutional financial interest, depending on the circumstances, the language might read:

- “CWRU [and hospital affiliate] is [are] the owners of the inventions being commercialized/used by this outside entity, and as such, could gain royalties” and/or;
- “CWRU [and hospital affiliate] has [have] an institutional official[s] with an interest in this outside entity.”

Disclosure: Faculty/Staff/Trainees

Disclosure to faculty/staff/trainees can be done at regular team/research meetings and/or by email communication to faculty/staff/trainees. The COI Office may request documentation of this disclosure process. Examples of documentation include copies of meeting minutes and/or email communications. Email documentation can be achieved by copying the COI Office secured mailbox: caseoic@case.edu

For the purposes of this guidance, “faculty/staff/trainees” includes all roles and positions on the conflicted research, including but not limited to: co-investigators, co-authors, academic advisees, students, fellows, residents, post-docs, and research assistants.

Sample Notification for Informing faculty/staff/trainees:

Dear [Faculty/Staff/Trainees],

I am writing to inform you that I:

*“serve as an officer with [entity/company/organization]” and/or;
“have an ownership interest in” and/or;
“receive compensation from” and/or;
“invented intellectual property being commercialized by an outside entity” or
“invented intellectual property being used in this research”*

I also receive research grant funding from [entity/company/organization] investigating [briefly describe the research area]. This relationship has been identified as having the potential to create a conflict of interest with my responsibilities as a faculty member. I have fully disclosed these interests to Case Western Reserve University (CWRU), and I have in place an approved plan for managing any potential conflicts arising from this involvement. To manage this financial and potential conflict, it is my responsibility to follow this management plan, which includes providing you with this notification.

I understand that your work on the project, [insert project name], should be for academic reasons to further your studies and/or your professional career endeavors. If at any time you have any concerns about whether your work is inappropriately focused toward my outside relationship(s), or that your ability to publish has been impeded in any way, I encourage you to contact [add from list of Resources for Faculty/Staff/Trainees as applicable].

Sincerely,

[Your Name][Your Title]

Human Subjects Research: Disclosure on Institutional Review Board (IRB) Documents

The COI Committee requires disclosure of your outside financial interest and/or any institutional interest(s) in the IRB-approved informed consent document(s) and IRB protocol application. Please follow all other IRB requirements regarding disclosure of outside interests. The Committee recommends that the following language be added to the COI disclosure on the informed consent document:

“This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study.”

According to guidance from the American Association of Medical Colleges (2001 AAMC Report), “the precise wording of disclosure in the consent form should be determined by the IRB, but should include an explanation of the fact that the financial interest in question has been reviewed by the COI committee, approved subject to committee oversight, and determined by both the committee and the IRB not to pose any additional significant risk to the welfare of research subjects or to the integrity of the research.”

Human Subjects Research: Role on IRB Project

The COI Committee focuses on the protection of human subjects when developing COI management plans. The AAMC (2001 Report) states, “Interactions between a conflicted researcher and the subjects participating in the proposed research must receive the strictest scrutiny because the interactions are fraught with ethical dilemmas and carry potential for harm. The restriction of a conflicted investigator’s role in the research project, adjusted to the level of anticipated risk, is the principal strategy for protection of subjects.”

The COI Committee generally requires (unless otherwise specified in your management plan) that you do not participate in subject selection, determination of eligibility and the informed consent process. In most cases (unless otherwise specified in your management plan), you will be permitted to answer questions from research participants about the research project. If there is a possibility that any of your clinical patients may meet eligibility criteria, you are required to limit your role to providing your patients’ information to the non-conflicted PI or other individual conducting recruitment.

Management plan elements are for the duration of the research study until all data are published and/or until the IRB protocols are closed completely, including for follow-up, whichever occurs later. If you begin or resume any IRB protocols related to any outside entity with which you have a conflict, you must notify the Conflict of Interest Office.

Animal Research Management

Conflicts of interest must not compromise the welfare of research animals or the integrity of the research review process. The Institutional Animal Care and Use Committee (IACUC) will be notified of your and any other investigators’ conflict of interest and provided a copy of associated management plans.

Conduct and Data Monitoring

The purpose of independent data monitoring is to assure objectivity and data integrity. The independent data monitor has the capability to take measures to protect the conduct, analysis, and reporting of research to help eliminate potential elements of possible bias due to your conflict of interest related to the research. The criteria for this role are an individual who does not have or report to anyone who has a conflict of interests with the related research.

A non-conflicted investigator has no conflict of interest with the project for the duration of the research/protocol. This includes when it is open for follow-up only or when all data is published, whichever is later. If these conditions are not met, then selection of another PI may be necessary to implement the requirements of the management plan.

There is not a “one-size-fits-all” management strategy to ensure integrity of the research or of the underlying data. The COI Committee may use one or more of the following strategies:

- Review of the study design to address potential bias arising from the outside interest.
- Oversight of the involvement of a conflicted individual in data collection.
- Oversight of the involvement of a conflicted individual in data analysis.
- Oversight of the involvement of a conflicted individual in data reporting.
- Appointment of a non-conflicted advocate for faculty/staff/trainees.

- Appointment of an independent data monitor.
- Review of authorship status.
- Designation of an independent data monitoring board.
- Provide copies of reports to the COI Committee, upon request.

Resources for Faculty/Staff/Trainees Working on Conflicted Research

The COI Committee recognizes that faculty/staff/trainees working on conflicted research should be made aware of resources available to them in case they have concerns about their activities on the research project and/or interference with academic/professional progress.

General Resources:

- Research Integrity Officer: Tracy Wilson-Holden, tracy.wilson-holden@case.edu, 216.368.6131
- COI Office: caseoic@case.edu, 216.368.5963
- Integrity Hotline: 1.866.483.9367 or go to the website: <https://www.caseintegrityhotline.com/>

The COI Committee may appoint as appropriate, additional alternate supervision. If this is the case, you are required to provide faculty/staff/trainees with their information.

Academic Advising

If you have students/advises who are working on conflicted research, you are required to:

- Ensure there will be no delay in the trainees' ability to publish.
- Ensure there will be no delay in the trainees' completion of their program of study/graduation.
- Inform the trainee of any sponsored project agreement terms and conditions that could affect their publication or career choices.
- Ensure that the trainees' thesis committee members are aware of your conflict of interest with the project.
- Provide the trainees the name(s) and contact information of resources for trainees working on conflicted research, in the event that the trainees have questions or concerns about their participation on the project.

Business Decisions and Relationships

Individuals and their family members/households are required to comply with all applicable policies, procedures, and practices related to vendor relations. These guidelines apply to the use of institutional resources, receipt and acceptance of gifts, and purchasing and business decisions. Information about CWRU policies and procedures is available at: <http://case.edu/policies/>

Business relationships and interactions should be free of actual or perceived conflicts of interest. If you and/or a family member have the potential to benefit, directly or indirectly, from a business decision or relationship with CWRU, you are expected to adhere to the appropriate and applicable policies and rules of conduct regarding balancing your individual interests and your University roles and responsibilities.

The following limitations and strategies are required of you in order to protect CWRU, its interests, and your outside interests/business relationships where there is a conflict of interest:

- Do not participate in any consideration, decision-making, negotiation or transactions on behalf of CWRU with your outside interest
- Do not use University resources (which includes, but is not limited to, University staff or trainees, laboratory or office equipment, laboratory or office supplies, University services, core facilities, University name or logo) to conduct business on behalf of your outside interest (without a service contract or research agreement)
- Do not sign-off on expenditure of invoices and/or quotes for payment of services provided to your outside interest performed at CWRU
- Do not disclose confidential information to your outside interest (unless covered by a nondisclosure or confidentiality agreement)
- Do not share biological material owned by the University with your outside interest (unless covered by a materials transfer agreement)
- Do not channel discoveries or share unpublished data with your outside interest (unless otherwise covered by a research or data usage agreement)
- Do not require or encourage CWRU faculty/staff/trainees to engage your outside interest for use of services
- Understand that your outside interest must follow CWRU processes concerning use of services or resources offered by CWRU and that you will not be involved in these processes
- Do not sign or negotiate any contracts with your outside interest on behalf of CWRU or its affiliates

Competitive Interests

If you engage in work or research with a direct competitor of your outside interest, you are required to inform the University, the competitor and the outside entity/organization of this relationship.

Monitoring: Implementation

The COI Office monitors management plans on a routine basis. Preparation for monitoring begins when a management plan is issued. Monitoring ensures that the requirements of the plan are understood and are being followed.

The COI Office ensures the monitoring of management plans by speaking with involved persons and requesting and reviewing information. At the time of monitoring, the COI Office works with individuals to review changes. Monitoring includes a discussion of planned projects or future directions that may impact the management plan.

Monitoring: Supporting Documentation

Individuals can assist monitoring by creating and maintaining supporting documents as they implement their plans. Documents that are regularly part of a management plan portfolio and that can be used to document implementation include the following:

- Documentation of Required Disclosure(s)
- Documentation that disclosure was made to faculty/staff/trainees working on the conflicted research. *Eg. Email, meeting minutes, disclosure letter.*
- Current Informed Consent Documents with current IRB approval stamp (unless the study is officially closed).
- Related publications or citations from the past year.
- Related presentation slides from the past year (only need the title slide and financial interest disclosure slide).
- Current IRB applications.
- Memos or other documentation related to data oversight or independent data monitoring.
- Communication or other correspondence regarding project oversight.

Commercialization

Please inform the COI Office if there is progress toward commercialization of your inventions or if research is conducted that utilizes licensed/optioned technology under a new or modified research plan, as an amendment to your management plan and/or a new management plan may be necessary.

Conclusion

The COI Committee wishes to reinforce that the management plan is designed to protect objectivity in research as there could be the perception of conflict of interest, and to protect the investigators, research staff, research participants, and the institutions involved.

Sharing, Distribution, and Reporting of COI Management Plans

The COI Office may share management plans in confidence with institutional officials, including your Dean, Department Chair or Supervisor and with appropriate regulatory committees (e.g., IRBs, IACUCs), as required for the implementation of this management plan.

CWRU will comply with DHHS regulations regarding providing to the awarding component financial conflict of interest reports as required under 42CFR50 Subpart F and 45CFR94, if applicable.

COI Office Contact Information

The COI Office welcomes comments, questions, and discussion regarding management plans and this guidance document. Please reach out to us with thoughts and ideas on how we can improve and assist you.

Email: caseoic@case.edu

Office Phone: 216.368.5963

Website: <http://case.edu/research/faculty-staff/compliance/coi/>