

## **Noncompliance**

The 2012 CWRU COI Policy (“the policy”) applies to all covered individuals (“individuals”), as defined in section I.A. of the policy. All covered individuals are required to comply with the policy.

Compliance with the policy does not relieve an individual from complying with other conflict of interest requirements, particularly those governing research, such as reporting requirements of Institutional Review Boards or the Institutional Animal Care and Use Committee; federal regulations governing federally sponsored research; or other research sponsor reporting requirements.

By completing or updating their annual CWRU Outside Financial Interest Disclosure, individuals are certifying they have read and understood the CWRU COI policy. For individual questions regarding the policy or its requirements, anyone accessing the electronic reporting process will be provided with a hyperlink to the policy as well as with contact information for Conflict of Interests Committee and the Committee Staff.

### Actions that constitute failure to comply with the policy:

In Section IV, the policy summarizes actions that constitute failure to comply with its requirements:

“Failure to comply with these policies includes failing to submit a required report, providing false information, omitting required information, failing to maintain confidentiality, failure to carry out duties prescribed by these policies, and refusal or failure to comply with a management plan adopted under these policies.”

### Sanctions:

According to Section IV of the 2012 CWRU COI policy, sanctions that may be applied in instances of non-compliance comprise “... the full range of University disciplinary procedures, including:

- a. Formal admonition.
- b. A letter in the individual's file indicating that the individual's good standing as a member of the University has been called into question.
- c. Ineligibility of the individual to apply for grants, IRB approval, or supervision of graduate or professional students or trainees.
- d. Additional sanctions per research funding agency may apply (such as requiring investigator financial conflict of interest training), up to and including sponsor suspension of funding per applicable federal regulations. The University will comply with federal financial conflict of interest requirements regarding non-compliance retrospective review and corrective action.
- e. Non-renewal of appointment.
- f. Termination of employment.”

## Role of the Conflict of Interests Committee

It is the responsibility of University leadership to ensure compliance with the 2012 COI policy. The Conflict of Interests Committee is a review and recommending body.

The 2012 CWRU COI policy designates the Conflict of Interests Committee as the review body for apparent instances of non-compliance (with the exception of failure to comply by the President or a member of the Board of Trustees, which must be reported to the Audit Committee of the Board of Trustees).

### The Noncompliance Process:

- The policy requires that apparent instances of non-compliance be communicated to the Conflict of Interests Committee Staff.
- The Chair of the Conflict of Interests Committee will be informed by the Committee Staff of apparent instances of non-compliance. The Chair will bring before the Conflict of Interests Committee all apparent instances of non-compliance that cannot be administratively ruled out or resolved. All administrative decisions regarding apparent instances of non-compliance will be presented to the Conflict of Interests Committee.
- Conflict of Interests Committee recommendations regarding administrative action(s) require a vote of the convened Committee (see below for a list of possible recommendations by the Conflict of Interests Committee).

### Responses by the Conflict of Interests Committee

The Conflict of Interests Committee may inform the apparently noncompliant individual of the requirement to complete the annual financial interest report, to respond to committee's requests for information, or to comply with a management document or with management plan monitoring. Such communication may take the following forms:

- Drafting a "letter of concern" from the Chair of the Conflict of Interests Committee to the individual.
- Copying the individual's supervisor, Chair and/or Dean on this correspondence. Compliance is the responsibility of the individual's supervisor, Chair or Dean as the first line of supervision.
- Scheduling short-term monitoring (if the individual has a management plan) to verify that the apparent instance of non-compliance has been corrected.
- Additional sanctions per research funding agency may apply (such as requiring investigator financial conflict of interest training), up to and including sponsor suspension of funding per applicable federal regulations. The University will comply with federal financial conflict of interest requirements regarding non-compliance retrospective review and corrective action.

The Conflict of Interests Committee is a recommending body. It is the role of the Conflict of Interests Committee to educate and inform the University community (as well as all individuals covered under the CWRU policy) of the mandates of the policy and the necessity for adherence to its provisions.

In responding to instances of non-compliance, the Conflict of Interests Committee may make recommendations which include but are not limited to the following:

- Recommend corrective education to inform the individual of the necessity of compliance with the policy and the possible consequences of noncompliance
- Notify the individual that additional administrative actions could be recommended, should the issue not be resolved.
- The COI Committee may recommend to the appropriate grants/contracts officer and/or regulatory body:
  - Suspension of the research project (e.g., CWRU IACUC protocol; CWRU or affiliate hospital IRB protocol).
  - Prohibition of the establishment of a sponsored project account.
  - Suspension or termination of the Investigator's eligibility for grant applications.
  - Suspension or termination of the Investigator's eligibility for IRB approval.
  - Additional sanctions per research funding agency, as applicable.

Refusal to cooperate:

For instances in which an individual refuses to comply, the following measures are taken in accordance with the policy:

The Conflict of Interests Committee refers the matter, along with its recommendations about how the matter should be handled, to the appropriate individual or body (e.g., the individual's supervisor, Chair or Dean as the first line of supervision).

Per the policy,

“In the case of the Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, and any other individual that the President designates as a senior ‘cabinet-level’ official, the Conflict of Interests Committee refers the matter to the President.” (Section IV)

Appeal:

The 2012 CWRU COI policy provides the following direction regarding the appeal process:

“If an individual other than a non-faculty employee is dissatisfied with a determination of the Conflict of Interests Committee to impose a corrective action plan or with administrative action by the Vice President for Research to suspend or refuse to approve a University research project, the individual may submit a written appeal to the Provost within 10 days of receipt of the determination. A non-faculty employee who is dissatisfied with a determination of the Conflict of Interests Committee may submit a written appeal to the Senior Vice President for Administration within 10 days of receipt of the decision.

If the Provost upholds the Conflict of Interests Committee's determination, the Provost's decision is final. If the Provost modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

If the Senior Vice President for Administration upholds the Conflict of Interests Committee's determination, the decision of the Senior Vice President for Administration is final. If the Senior Vice President for Administration modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

Grievance proceedings are conducted in accordance with the procedures provided in the University Faculty Handbook and the Human Resources Policy Manual."

The Conflict of Interests Committee will request any final communications regarding an appeal be provided to the Chair of the Conflict of Interests Committee in order for the Committee to be duly informed of the outcome of said appeal. The Conflict of Interests Committee Staff will maintain all communications regarding the final determination of any appeal in the relevant individual's file.