

Procedures for Case Western Reserve University Outside Interest Review and Management

Training Requirements

Case Western Reserve University (CWRU) will comply with federal regulations [42 CFR Part 50 Subpart F](#) regarding providing training on federal requirements for investigators applying for and engaged in PHS-funded research. Critical training points are included as part of the online financial interest disclosure form. These critical training points include a link to the institution's policy, the federal regulation, and the investigator's disclosure responsibilities.

The Conflict of Interests Committee staff engages in regular outreach to the community through newsletters, online announcements, and in-person training offered to investigators and research staff.

Additional FCOI-related resources can be found on the NIH's FCOI Training site at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>.

Financial conflict of interest report to DHHS Awarding Component, including retrospective review

CWRU will continue to use the eRA Commons Financial Conflict of Interest (FCOI) online reporting system for the initiation and annual updating of investigator FCOI with PHS-funded projects prior to the expenditure of any funds under a PHS-funded research project, as required by [42 CFR 50.605\(b\)](#). The eRA Commons FCOI module will also be used to rescind (update or correct) or revise (report retrospective review and/or mitigation, as required). The report will include project number, PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the investigator with the financial conflict of interest; name of the entity with which the Investigator has a financial conflict of interest; nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value; a description of how the financial interest relates to the PHS-funded research and the basis for the CWRU's determination that the financial interest conflicts with such research and a description of key elements of the management plan.

Management plan key elements will include the role and principal duties of the conflicted investigator in the research project, conditions of the management plan, how the management plan is designed to safeguard objectivity in the research project, confirmation of the investigator's agreement to the management plan, how the management plan will be monitored to ensure investigator compliance and other information as needed. For any significant financial interest that CWRU identifies as conflicting during an ongoing PHS-funded research project, CWRU will provide to the PHS Awarding Component, within 60 days, an FCOI report.

If a financial conflict of interest related to PHS-funded research is not identified or managed in a timely manner including failure by the investigator to disclose a financial conflict of interest; failure by the institution to review or manage such a financial conflict of interest; or failure by the investigator to comply with a conflict of interest management plan, CWRU will, within 120 days of the institution's determination of non-compliance, complete a retrospective review of the investigator's activities and the PHS funded research project to determine whether any PHS funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct or reporting of such research. The institution is required to document the retrospective review. Based on the results of the retrospective review, if appropriate, CWRU will update the previously submitted FCOI report,

specifying the actions that will be taken to manage the conflict of interest going forward. If bias is found, the institution is required to notify the PHS awarding component promptly and submit a mitigation report to the PHS Awarding Component.

Details on Travel Expense Disclosure

For recipients of PHS awards, disclosure of travel expenses and reimbursement is required for travel that is not reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education within the United States as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education. This exclusion is limited to entities located within the United States, and therefore, when these interests are associated with the governments of another country, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States) or foreign institutions of higher education, they must be disclosed.

Disclosure of the nature of the travel will be accomplished on the annual disclosure form. Disclosure is required of the duration/ date(s) of the trip (s), the purpose(s) of the trip(s), the identity(ies) of the sponsor/organizer, and the destination(s).

The Conflict of Interests Committee may require additional information not captured on the formal request, including an estimate of monetary value, in order to determine whether the travel may constitute a financial conflict of interest with PHS funded research.

Disclosure Procedure Details

Whenever, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest to the Institution, the Conflict of Interests Committee of CWRU, within 60 days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, CWRU may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

The information disclosed on individual conflict of interest forms is used in carrying out the institutional conflict of interest policy. Approved management plans can include stipulations on an individual's role in any human subjects research which cannot be weakened by an IRB, although IRB can require more stringent conditions.

Monitoring of Management Plans

The CWRU Conflict of Interests Committee monitors management plans on a routine basis. Monitoring ensures that the requirements of the plan are understood and followed, and to assist the faculty, staff member, or student in implementing the plan.

Mitigation

Mitigation plan and review will comply with federal regulations [42 CFR 50.604\(b\)](#) regarding providing training on federal requirements for investigators applying for and engaged in PHS-funded research. whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to

constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 60 days of identifying an FCOI, review the significant financial interest, determine whether it is related to PHS-funded research, and determine whether a financial conflict of interest exists, and if so implement on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

In addition, within 120 days of the Institution's determination of noncompliance, the institution will complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The mitigation report will include project number, project title, PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the investigator with the financial conflict of interest; name of the entity with which the Investigator has a financial conflict of interest; reason for the retrospective review, detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed), findings of the review, and conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a *description of the impact of the bias* on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review. Whenever an Institution implements a management plan pursuant to this subpart, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Additional Mitigation for Clinical Research

In any case in which U.S. Department of Health and Human Services (HHS) determines that a PHS-funded project including clinical research, with the purpose to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by 42 CFR 50.606 (c), the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations .

Public Reporting

CWRU will comply with federal financial conflict of interest regulations regarding making publicly available information on identified financial conflicts of interest held by senior/key personnel on PHS-funded research. CWRU will respond meaningfully to any requestor within five business days of

information concerning any significant financial interest related to PHS funding. The response will include the following criteria:

- a. The significant financial interest was disclosed and is still held by the senior/key personnel;
- b. CWRU determines that the significant financial interest is related to the PHS-funded research; and
- c. CWRU determines that the significant financial interest is a financial conflict of interest.

Subrecipient Requirements

CWRU has a process to review and address subrecipient requirements for review of financial conflicts of interest related to PHS-funded research. CWRU also includes an exhibit in all contracts with subrecipients that addresses subrecipient assurance with implemented policy on conflict of interest that complies with [42 CFR Part 50.604\(c\)\(a\)\(1\)\(i\)-\(iii\)](#). This exhibit requests that the subrecipient certifies to the best of subrecipient's knowledge that all financial disclosures required for investigators participating in this project have been made. If subrecipient does not have a financial interest disclosure form that complies with FCOI regulations cited above, it agrees to develop one. Disclosure must be made by key personnel, including the Project Director/Principal Investigator, and all other persons have responsibility for the design, conduct, or reporting of the research. Prior to the subrecipient's expenditure of any funds under this award, subrecipient agrees to submit to CWRU any FCOI reports as required under [42 CFR Part 50.604\(c\)\(a\)\(1\)\(i\)-\(iii\)](#). For any FCOIs identified subsequent to the initial report under this award, subrecipient will provide to CWRU within 30 days any FCOI reports as required by FCOI regulations cited above.

Independent contractors will be required to disclose using the subrecipient requirements, as above, if the independent contractor is also listed as investigator/key personnel on a PHS-funded award.

Record Retention

CWRU will maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in [45 CFR 75.361](#) for different situations.