Who is required to complete an annual Conflict of Interest/Conflict of Commitment disclosure?

CSU policy requires that all Faculty and Administrative Professional employees complete an annual disclosure, including those who are part-time, temporary, off-campus or on leave. Those who are listed as a PI, Co-PI or key personnel on a PHS agency research grant are also required to complete a disclosure regardless of the employee type (for example a postdoc may need to disclose as key personnel). Other employees may be asked to complete a disclosure as deemed necessary by their unit head. See the CSU policy on Conflict of Interest and Conflict of Commitment in the Academic Faculty & Administrative Professional Manual:

http://www.facultycouncil.colostate.edu/files/manual/sectiond.htm#D.7.6

Definitions

**Entity**: is an external business, company, or other such organization, and includes (but is not limited to) any partnership, corporation, limited liability corporation, unincorporated association, or other institution or organization, whether for-profit, academic, or professional.

**Financial Conflict of Interest**: a Financial Conflict of Interest exists when CSU determines that an Investigator’s Significant Financial Interest is related to a funded research project and could directly and significantly affect the design, conduct or reporting of the funded research, or present the appearance thereof.

**Immediate Family Member**: includes an Investigator’s spouse, domestic or civil union partner, and dependent children.

**Institutional Responsibilities**: Institutional Responsibilities include professional activities that relate to an Investigator’s responsibilities on behalf of CSU, such as research, teaching, institutional committee memberships, professional practice, and administrative activities and responsibilities for CSU.

**Investigator**: includes anyone responsible for the design, conduct, or reporting of research, regardless of title or position, and their Immediate Family Members.

What is a Significant Financial Interest (SFI)?

An external significant financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator’s Immediate Family Members) related to their Institutional Responsibilities, when aggregated for the 12 months preceding the disclosure date exceeds $5,000 from a single Entity:
1. Remuneration, compensation, and/or other payments for services (e.g., consulting, speaking)
2. Equity interests in a publicly-traded entity
3. Equity interests in a non-publicly-traded entity (e.g., a start-up company)
4. Any Intellectual property rights and interests
5. Sponsored or reimbursed travel **** see note #6 below for travel exemptions

What is NOT a SFI?

1. Salary, royalties or other remuneration paid by CSU to the Investigator if the Investigator is currently employed or otherwise appointed by the University
2. Intellectual property rights assigned to CSU and agreements to share in royalties related to such rights
3. Equity interests through investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles
4. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education
5. Income from service on advisory committees or review panels for a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education
6. Sponsored or reimbursed travel sponsored or paid by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education

Which outside professional commitments are exempt from reporting?

The following activities, when they are related to the normal course of work as a faculty/AP employee, do not count as outside professional commitments. The activities listed below do not need to be reported unless they are compensated by a business entity beyond expense reimbursement. Receipt of royalties for scholarly publications does not constitute "compensation by a business entity" for purposes of this policy.
Regardless of compensation, these activities must not interfere with the performance of regular employment duties or compete with coursework offered by the University or services offered by the employee's unit.

- Preparing scholarly or artistic works
• Peer review of articles and grant proposals
• Attendance and presentations at professional meetings (and other similar gatherings)
• Serving on advisory committees or evaluation panels for governmental agencies, non-profit higher education institutions or non-profit entities organized solely for educational, religious, philanthropic, or research purposes (with the exception of non-profit entities created by for-profit corporations)
• Giving occasional lectures and speeches, participation in colloquia, symposia, site visits, study sections, and similar gatherings sponsored by governmental agencies, non-profit higher education institutions or non-profit entities organized solely for educational, religious, philanthropic, or research purposes (with the exception of non-profit entities created by for-profit corporations)
• Ad hoc refereeing of manuscripts

What sponsored or reimbursed travel must I report, and when must I report it?

Within 30 days of its occurrence, you must report sponsored or reimbursed travel taken by you, your spouse, or dependent children that is related to your institutional responsibilities, unless the travel is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a) (see note #6 above), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

When do I need a Management Plan?

Management plans are implemented when there appears to be overlap between an individual’s outside relationships and/or interests and their Northwestern responsibilities. The purpose of a management plan is to enhance transparency and create separation between Northwestern work and the work an individual may be doing outside of the university in order to avoid even the appearance that decision making was biased or influenced by that outside interest. Management plans strategies can vary depending on the circumstance. If a Financial Conflict of Interest determination is made, the conflict of interest sub-committee (working with Investigators and others as needed) develop a conflict of interest management plan to manage, reduce, or eliminate the Financial Conflict of Interest. Conflict of interest management plans are strategies designed to mitigate the potential for an Investigator’s Significant Financial Interests to impact or bias research objectivity and/or the safety or welfare of human research participants.

What is included in a management plan?

Conflict of interest management plans could include:

• Recusal from decisions involving the outside company the person has a relationship with
Parameters around using Northwestern resources for activities with an outside entity
Restrictions on using direct reports or trainees in those outside activities without proper agreements and/or reporting line changes in place

What are some common management plan strategies?

- Disclosure to collaborators and team members,
- Disclosure in publications, presentations, and press releases
- Disclosure in informed consent documents (as applicable)

Additional conflict of interest management strategies may be employed depending on the nature of the Financial Conflict of Interest and the nature of the research activity. In extreme cases, an Investigator may be prohibited from participating in research due to the level and extent of Significant Financial Interests deemed to present a Financial Conflict of Interest relative to specific research activity.

Is CSU responsible for external reporting?

Some external sponsors, such as PHS, require CSU to provide initial and ongoing reports relative to Investigator’s Financial Conflict of Interest determinations as they relate to specific research activities. For Financial Conflicts of Interests relative to PHS-funded research, CSU must perform the required conflict of interest reporting prior to the expenditure of funds for new projects, within 60 days of newly-determined Financial Conflicts of Interest identified during the life of a project, and on an annual basis thereafter prior to progress report submission during the life of a project. In addition, PHS requires CSU to make available to the public, upon request, specific information regarding Financial Conflicts of Interest determined for senior and key personnel relative to PHS-funded research. CSU is required to provide specific information relative to such public requests within five business days of the request.