COI Management

COI Plan Setup

A Good COI Plan Must Answer These Questions

- Who will have oversight for your plan?
- Who will educate the organization on COI?
- Who must disclose COI?
- What must be disclosed?
- When should COI be disclosed?
- How will COI be disclosed?
- Who will review disclosed COI and with what criteria?
- Who will develop needed management plans and how will they be developed?
- Who will audit and/or monitor to ensure compliance with disclosure requirements and management plan implementation?

Who will have oversight for your COI plan?

Usually corporate compliance, HR, operations, or a committee will lead. Avenues for collaboration with other departments must be open as well: Compliance, HR, legal, researchers, audit, finance, department leaders.

Who will educate the organization on COI?

Those responsible for the COI plan should approve of any training. COI-related content should be included in annual compliance training. Develop an ongoing communication plan to get the word out. Set up a webpage or intranet page as a one-stop location for policy info, FAQs, forms, etc.

Who must disclose COI?

All employees or employees most likely to pose a risk. This depends on the industry such as physicians for healthcare, faculty for schools, engineers for manufacturing, researchers for pharmaceuticals, or sales people for commerce.

What must be disclosed?

Names of other current employers, any non-profits the respondent or a family member serve with as a board member, names of businesses which the respondent or a family member owns or is a majority shareholder. Provide clear communication and offer examples about what a "secondary interest" might be. See the above list "Where conflicts could arise..." for examples to highlight.

Where conflicts could arise

- Serving on an external board
- Having personal relationships (internal, supplier, or competitor)
- Holding financial interests
- Receiving gifts or entertainment
- Working other jobs
- Running for or holding office
- Publications, teaching, or presentations

Possible Uncovered Conflicts

- Unsanctioned speaker fees
- Unreported gifts from vendors or suppliers
- Undisclosed ties or influence for decisions, recommendations and research
- Improper use of expense accounts
- Direct or indirect ownership interest
- Review and advice related to proprietary information

Factors to consider when evaluating risk from a disclosed COI

- Position & influence of discloser
- Type of outside entity
- Nature of relationship with outside entity
  Remuneration from outside entity
- Similarity between outside activity and job responsibility
- Risk of reputational harm if it went wrong
- Time that would be devoted to outside activity

How will COI be disclosed?

An internal software resource or 3rd-party software allows you to operate at scale. A paper process can get you started, but can only carry you so far.

When should COI be disclosed?

Annually, and as an employee has new circumstances that create a potential COI such as getting a promotion.

Who will review disclosures and against what criteria?

Corporate compliance, legal, or HR in some cases. Criteria should be well-defined with a clear risk threshold set, such as a dollar amount, an attribute, or another quanitative value.

Who will develop needed management plans and how will they be developed?

Those you appoint responsible for the COI plan should develop an outline of the steps needed to manage potential conflicts based upon established policy and procedure. Create a basic management plan template which can be adjusted for several situations. Make sure these can be easily audited.

Setting a risk threshold

To combat misinformation, a clearly stated risk threshold must be established and the thinking behind it should be understood to ensure buy-in. Consider these examples:

Define how much financial interest one can have in a supplier.

Determine how far an employee can influence the hiring of a friend or family member such as if they can be a reference or if they can be the interviewer.

Set a limit on a gift's cost when it is given by an external sales representative.

Who will audit and/or monitor to ensure compliance with disclosure requirements and management plan implementation?

Both tasks can be managed by the same parties or they can be handled by subgroups. Disclosure requirement monitoring requires a team to monitor the "big picture" for an industry and ensure disclosures are completed by the necessary people. Monitoring a management plan requires a situation-to-situation focus with ongoing feedback assessing whether a risk threshold has been crossed.