Valparaiso University
Institutional Review Board (IRB)
Office of Sponsored and Student Research

INSTITUTIONAL REVIEW BOARD (IRB)
CONFLICTS OF INTEREST

1. Purpose

Conflicts of interest (COI) take many forms and can interfere with ethical conduct of research. This document outlines the types of COIs as well as the procedures for reporting them.

2. Types of Conflicts of Interest

<u>Academic Conflicts of Interest or Intellectual Bias</u>

This type of COI involves interfering with the peer review process. This takes the form of actions such as responding positively to a study that supports a method that the individual personally favors or postponing the publication of one's own or a competitor's study for some sort of intellectual or academic gain.

<u>Conflicts of Commitment</u>

Also called conflicts of effort or conflicts of obligation, this type of COI occurs when the time spent on a secondary activity interferes with the expectation of one's primary employer.

At Valparaiso University, the workload is based upon the number of class hours taught, and faculty request a course release to engage in research projects to allow for time to be used toward such an activity.

<u>Conflicts of Conscience</u>

This type of COI occurs when an individual's personal beliefs influence the ability to be objective in the research. This can include things such as political, religious, or philosophical beliefs.

<u>Financial Conflicts of Interest</u>

A financial COI can take many forms. These COIs involve some type of financial payment that influences an individual to prefer one outcome over another. These payments could be consulting fees, equity in a company, and general monetary rewards. Financial COIs are considered tangible conflicts of interest, and can affect many aspects of research and publication alike.

3. Federal Regulations on Financial Conflicts of Interests

The federal regulations state that any significant financial COIs must be disclosed to the individual's institution; this includes salary or payment for services from another institution, stocks, and intellectual property rights. "Significant" is considered to be a financial amount that is or is expected to be greater than or equal to $10,000, or greater than or equal to 5% ownership in a single entity, for the investigator as well as their family members.

A "family member" includes the investigator's spouse, and whether related by blood or by marriage: parents, grandparents, great grandparents, siblings, children (genetic or adopted), grandchildren, great grandchildren, and the spouses of any of these individuals.

The full regulations on COIs can be found at this link.

4. Managing Conflicts of Interest

While having no COIs is ideal, it is not always possible to eliminate COIs entirely. However, there are a few ways to manage them. The first method is the disclosure of COIs, including a disclosure in the informed consent process, oral presentations, and publications to ensure full awareness of the relationship. The research plan could also be modified, including changing the site(s) where the research is to be conducted.

Portions of the research may also be monitored by independent reviewers, including correspondence with the sponsor of the research and oversight of the research process itself.

While not always possible, divesting any significant financial interests and/or severing professional or business relationships that cause actual or potential COIs are two other methods of managing these conflicts.

5. Conflicts of Interest at the IRB Level

COIs for individual IRB members can arise for a number of reasons. The IRB member could be an investigator on the research to be reviewed, have significant financial interest in the sponsor of the research, or have perceived or actual loyalty to colleagues submitting a review. If the IRB member has close ties to the area of research to be reviewed, it may cause them to be either more lenient or more critical in their appraisal of the research, and may also occur when the work of a member could be impacted by the decision made. Additionally, personal agendas or strong personal beliefs can influence the decision an IRB member makes, and their ability to perform the duties expected of them could be impacted by their non-IRB roles.

COIs at the institutional level, however, can also influence the decision-making process of the IRB. There may be pressure or desire to protect the institution, or concerns about the reputation or prestige of the institution. This can cause a heavy focus on the promotion of research that leads to a less critical expectation for the protection of subjects, or cause research to be denied out of concern for potential liability rather than actual ethical considerations.

Some other effects that an institution could have on an IRB is an undervaluing of the IRB itself or if there is pressure for a speedy review process. This could cause the IRB to change the ways in which they review applications to either increase their perceived value or to ensure a quick review turnaround. Additionally, the values of both the institution and the community itself could influence the decisions made, and any financial interests of the institution can create financial COIs in the IRB process.

6. Managing Conflicts of Interest at the IRB Level

There are a few different methods for COIs to be managed at the IRB level. First, members are required to recuse themselves from voting upon protocols that risk the influence of their COI. Depending on the situation, the IRB Chair may request that the IRB members with the COIs recuse themselves from the discussion of the application.