SOP 304: Conflict of Interest

Terms and Abbreviations

COI: Conflict of Interest
IRB: Institutional Review Board
PI: Principal Investigator
SPI: Student Principal Investigator
UWM: University of Wisconsin-Milwaukee

Overview

Researchers inherently have a conflict of interest in their research proposals, as the research frequently has a direct impact on the researcher's professional or academic career. Additionally, successful completion of research proposals is vital to tenure, promotion, publication, and completion of degrees. In some cases, researchers may also have a financial conflict of interest in the outcome of the research.

IRB members may have a conflict of interest due to their involvement as a researcher in a protocol under review, due to personal or professional relationships with the researcher(s), or due to a financial interest in the proposed research.

UWM may have an institutional conflict of interest when the institution is better or worse off depending on the outcome of the research.

The IRB has the responsibility to ensure that these potential conflicts of interest do not negatively impact the rights or welfare of participants, or the fair and unbiased review of research proposals.

Details and Procedures

A Conflict of Interest occurs whenever an individual has incentive to act in a way to put their own personal or professional interests ahead of ethical considerations. COI also occurs when there is any appearance that an individual's actions may be biased. A COI may be personal, professional, or financial.

Identification of a potential COI does not confer any judgment about the moral character of the person identified to have a COI, but rather recognizes that the *opportunity* for biased conduct or wrongdoing exists. Measures taken to manage these COIs vary with the degree and type of COI.

Researcher COI

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research asserted that "… investigators are always in positions of potential conflict by virtue of their concern with the pursuit of knowledge as well as the welfare of the human subjects of their

research." (1978). This inherent COI exists in all studies, and may or may not require any special management to ensure the protection of participants' rights and welfare.

Examples of other COIs may occur in studies where the researcher:

- Stands to accrue a significant financial benefit from the research (e.g. devices that may be patented and/or sold for a profit if successful)
- Has a relationship with the potential participants (e.g. instructors recruiting their own students)

In each protocol review, the IRB notes any potential COI that could impact the rights or welfare of participants, and may require additional safeguards to minimize this impact.

For research involving entities for which the PI has a financial COI disclosed to the university, the PI must have a COI management plan reviewed and approved by the UWM COI committee and a copy should be shared with the UWM IRB for relevant studies.

Examples of potential actions the IRB may take to manage COIs:

- Require that the researcher disclose the COI to participants (typically in the informed consent document)
- Require that the researcher with the COI not participate in participant recruitment or consent activities
- Require the inclusion of an unbiased co-investigator on the study team
- Observe or monitor the consent process

Investigators may choose to manage their own COI. Examples of self-management may include:

- Having someone else conduct the research
- Divesting financial interests

IRB Member COI

COIs may exist in studies where the IRB member:

- Is the PI or a co-investigator
- Is the faculty member overseeing a SPI's project
- Has a personal relationship (either positive or negative) with any member of the study team, such that the member feels it may be difficult to provide an unbiased review
- A power differential exists (e.g. the researcher is Chair of the IRB member's department)
- May benefit financially from the study in some way
- Believes for any other reason that they are unable to perform an objective review, or that others may perceive the review as biased.

Managing COI in Studies Undergoing Full Board Review

- IRB members must disclose any known potential COI to the Chair at the start of the IRB meeting.
- IRB members do not vote on research protocols in which they may have conflicting interests.

- The member may be asked to recuse (leave the room) for the duration of the discussion and vote on that research protocol if the member's presence could create a bias.

Managing COI in Studies Undergoing Expedited Review

- IRB members will not be assigned as expedited reviewers for any study where there is an obvious COI.
- If an IRB member is assigned to review a study for which they have a COI, the member must notify IRB office staff and request that the study be assigned to a different reviewer. The member may simply state that they are unable to review the protocol, and do not need to disclose the nature of the COI to the IRB office staff.

Institutional COI

To manage institutional conflicts of interest, the IRB functions independently from the university as an independent board whose determinations are not dictated or influenced by anyone outside the IRB. Upper-level administrators may not be voting members of the IRB, and do not attend meetings where there may be an institutional COI.

The potential for hierarchical COI for the IRB office staff is also present. This COI is managed by having an organizational structure where the IRB office is not under any department or division charged with promoting or bringing additional research to campus, but is instead a part of University Safety and Assurances, under the Division of Finance and Administrative Affairs.

If these structural measures are not sufficient to manage an institutional conflict of interest for a specific protocol, other measures may be implemented, such as hiring an external IRB to review and oversee the conduct of the study, or hiring an external individual or organization to conduct the research.

References

45 CFR 46.107

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Report and recommendations: Institutional review boards (DHEW [OS] 78-00008). Washington, DC: Department of Health, Education, and Welfare; 1978. Accessed via https://repository.library.georgetown.edu/bitstream/handle/10822/778625/ohrp_institutional_review_boards_1978.pdf?sequence=1&isAllowed=y

Revision History

Version	Date	Summary of Changes
1	2 Jul 2020	Initial version