Guidance: Conflict of interest and human subject research

Overview

The Institutional Review Board [IRB] must ensure that financial or other business interests do not compromise the protection of human subjects in research.

The regulations protecting human research subjects are based on the ethical principles described in the Belmont Report. The Respect for Persons principle maintains that individuals should be treated as autonomous agents and demands that subjects enter into the research voluntarily and with adequate information.

If an investigator on the study team has an actual, potential, or perceived conflict of interest, this information must be disclosed to the IRB, who may require disclosure to potential participants.

Definitions

Conflict of Interest [COI]: refers to a divergence between an individual's private interests and his or her professional obligations to Northeastern such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.

Conflict of Commitment: a situation where the individual employee's outside activity interferes with or compromises, or appears to compromise, the employee's ability to fulfill her or his obligations to the university.

Family: For the purposes of this policy, "family" refers to an employee's spouse, domestic partners, children, parents, siblings, grandparents, parents-in-law, brothers-in-law, sisters-in-law or member of one's household.

Investigator: For the purposes of this guidance, "investigator" refers to any member of the research team.

Principal Investigator: The person who is responsible for the scientific and technical direction of the entire study (for example, for all sites of a multi-site study).

Management Plans: Conflict of interest management plans are written documents or statements that enhance transparency and create separation between an employee's personal activities and their university work in order to avoid the appearance of impropriety in university

decision-making or research. The document describes how COIs will be managed, monitored, or avoided.

Conflict of Interest [COI]

A conflict of interest (COI) exists when an individual or institution has two or more obligations or interests that may compete with each other. Conflicts of Interest in research occur when an Investigator has a significant financial interest or relationship that could be impacted by (or impact) the outcome of the research.

> The NIH defines a financial COI as "when the recipient's designated official(s) reasonably determines that an investigators significant financial interest could directly and significantly affect the design, conduct, or reporting of the [Public Health Service (PHS)]-funded research."

Examples of COIs

Potential conflicts of interest in research involving human subjects may include, but are not limited to:

- An investigator or family member participates in research on a technology, process or product owned by a business in which the faculty member holds a financial interest (including consulting fees, stock, equity interests, etc. even if they do not yet have a fair market value).
- An investigator participates in research on a technology, process or product developed by that Investigator, for which they hold a patent.
- An Investigator or family member has a financial or other business interest in an entity which is supplying funding, materials, products, or equipment for the current research project.
- An ivestigator or family member serves on the Board of Directors of a business which is supplying funding, materials, products, or equipment for the current research project.
- An Investigator receives consulting income from an entity that is funding the current research project.

> **42 CFR 50, subpart F, "Promoting Objectivity in Research."** require institutions that are recipients of NIH (or PHS) funds to have policies in place to identify and manage any financial conflicts of interest. Investigators must disclose to the institution their financial interests and institutions must determine whether these interests create a financial conflict of interest related to the research. If such a conflict exists, the institution must put into place a plan to mitigate or manage the conflict.

COI Management Plans

Given the potential for a COI to affect human subjects protections, IRBs must be aware of any investigator COI and determine that adequate measures are in place to manage the conflict. An adequate management strategy is one that minimizes the risk of potential harm caused by a conflicted investigator's actions and preserves the scientific integrity of the data yet does not unduly interfere with the ability of the research to be conducted.

The purpose of a COI management plan is to:

1. Accurately describe the potential conflicts in writing
2. Create explicit agreements to protect against actual conflicts
3. Facilitate oversight

In assessing the adequacy of any management plan, the IRB will need to understand the role of the conflicted Investigator in conducting the research, as well as how actions taken by that investigator in the research process might either increase the risk of harm to subjects or impact scientific integrity of the research.

Roles & Responsibilities

Principal Investigator [PI]: It is the responsibility of a PI to report any real or potential conflicts of interests of the PI or any study personnel in compliance with COI policies and management plans and to inform the entire study team and all research subjects of any COI related to a research study.

Conflicted Investigators' questionable objectivity may (intentionally or subconsciously) incentivize them to enroll subjects that do not meet eligibility requirements or to incorrectly attribute the causality of adverse events, or may bias the presentation of risks and benefits when obtaining informed consent or insert bias into the analysis of the data or reporting of the research.

IRB: Conflicts of interest directly affect an institutional review board's (IRB's) ability to approve research.

- The IRB is to determine if the management plan is sufficient or if additional management strategies are needed to protect human subjects.
- The IRB may require additional safeguards, restrictions, disclosures, or access to non-conflicted individuals when, in the IRB's judgment, such measures would add protection to the rights and welfare of subjects.
- The research consent form provided to subjects must include an appropriate description of any relationship that might be perceived as a potential conflict of interest. This requirement is consistent with §46.109(b).

> §46.109(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

Suggested consent form language when disclosing a COI

"This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study."

References

Code of Federal Regulations, Title 42, Part 50 – Subpart F

Code of Federal Regulations, Title 45, Part 46 – Subpart A

National Institutes of Health

SMART IRB