
Yale University Human Research Protection Program

HRPP Policy 500 Disclosures and Management of Personal Interests in Human Research

Responsible Office	Office of Research Administration	Effective Date	07/26/2002
Responsible Official	Human Research Protection Program Director	Last Revised	11Dec2017

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Scope

This policy applies to all faculty, staff and students who

- 1) serve as members of a research reviewing committee, or who
- 2) are responsible for the design, conduct or reporting of a human research project. The Principal Investigator (Project Director), upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

These individuals include, but are not limited to, all researchers, departmental Chairs or their designees, Yale IRB members, non-voting IRB meeting attendees, consultants and administrative personnel (staff) who engage in the review and deliberation of human research protocols submitted to the IRB.

Policy Statement

The University and its researchers have ethical obligations to honor the rights and protect the safety of persons who participate in research conducted at the University. Significant Financial Interests (SFIs) held by those conducting the research may compromise the fulfillment of those ethical obligations and the well-being of the research subjects, as well as the integrity of the related research. A conflict exists when a SFI could directly and significantly impact the individual's ability to carry out their University responsibilities without undue bias. Accordingly, any person with an unmanaged conflict of interest is prohibited from participating in the conduct of such research. In addition, research involving human subjects where there is a financial conflict of interest may only go forward if the design and circumstances of the human subjects research are such that they serve to protect both the human subjects and the objectivity of the data obtained. For example, research that includes multiple independent sites, or where the intervention or choice of device is blinded to the investigators, has an independent data and safety monitoring board, or has other such protective elements, may be allowed to proceed with an appropriate conflict of interest management plan. In order to address these special concerns, when human subjects are involved in the research, conflict of interest review will be coordinated with the Yale Conflict of Interest Committee. Researchers must make protocol-related conflicts known to the IRB.

The IRB is responsible for evaluating interests specifically related to human research projects and determining whether or not an interest may adversely affect the rights or welfare of research volunteers. The IRB is also responsible for ensuring that the research is conducted without influence or bias and that when necessary, appropriate mechanisms are in place to protect the rights and welfare of research participants and the integrity of the research pursuant to Food and Drug Administration (FDA 21 CFR 54)

and Public Health Services regulations (42 CFR § 50.603; 45 CFR § 94.3), National Science Foundation requirements (NSF Award and Administration Guide, IV.A.) and [University policy](#).

Reason for the Policy

All members of the Yale University research community should be sensitive to the potential impacts of financial and/or non-financial relationships with sponsors or other external entities on the conduct or review of research and the participation and protection of human research participants

A conflict of interest exists when an individual has a significant financial interest (SFI) that could directly and significantly affect his or her human research activities. Generally, this will be when the external interest provides an **incentive** to affect the individual's conduct of his or her human research activities and when the individual has the **opportunity** to affect the human research decision or other activity (for example, because he or she is the decision-maker or the principal investigator for a research project). Conflicts of interest can arise naturally from an individual's engagement with the world outside the University, and the mere existence of a conflict of interest does not necessarily imply wrongdoing on anyone's part. When conflicts of interest do arise, however, they must be recognized, disclosed and either properly managed or eliminated.

Conflicts of interest related to research involving human subjects pose special concerns. The University and its researchers have ethical obligations to honor the rights and protect the safety of persons who participate in research conducted at the University. Significant financial interests held by those conducting the research or with the sponsor of the research may compromise or appear to compromise the fulfillment of those ethical obligations and the well-being of the research subjects, as well as the integrity of the related research. Participation by any individual responsible for the design, conduct or reporting of research involving human subjects and holding a related significant financial interest that may be affected by the research must receive especially rigorous review and must not compromise the objectivity of the research or the well-being of research subjects.

This policy helps to ensure that known SFIs related to a specific protocol are disclosed to the IRB so that the IRB can fulfill its obligations to:

- 1) ensure that SFIs that compromise the protection of human research participants or the integrity of the research are managed, reduced or eliminated, and
- 2) ensure, when necessary, that the informed consent process provides potential research participants with the facts necessary to make a knowledgeable and sound decision as to whether or not they wish to participate in the research study.

Definitions

Conflict of Interest

A conflict of interest in human research exists when either an individual (or his/her immediate family member) or an institution has an external interest that affects or may provide an incentive to affect actions or decisions related to the conduct, review or approval of the research. A conflict of interest may be financial or non-financial in nature.

Immediate Family

Spouse or dependent children.

Non-Financial Relationship or Interest

A non-financial interest that may affect the conduct of research and is deemed significant by Yale University Policy on Conflict of Interest and Conflict of Commitment

Any relationship, position or the promise of a position with sponsors, other external entities or persons that might influence or appear to influence the outcome of, or a decision related to, a research project involving human subjects. Such relationships include, but are not limited to, 1) an unpaid directorship or

management position; 2) a board membership; 3) an unpaid consulting relationship; or 4) a personal relationship.

Non-financial interests also include intellectual property rights, including patents, patent applications and copyrights when there is the promise of monetary reward, but the value is presently unknown.

When evaluating such non-financial interests or relationships, the IRB Chair/Vice Chair, Designee or Committee will seek to determine the ability of the parties to remain objective in light of the interests or relationships.

Significant Financial Interest

For research funded by the U.S. Public Health Service, a financial interest exceeding \$5,000 is significant (42 CFR § 50.603; 45 CFR § 94.3). For all other research an SFI is a financial interest that exceeds \$10,000 (NSF Award and Administration Guide, IV.A.; [University policy](#)).

Related Information

- 500 PR1: Procedures for Disclosing Financial and Non-Financial Interests Related to Research
- 500 PR2: Procedure for Review of Disclosures of Financial and Non-Financial Interests Related to Human Research Projects
- 500 FR 1: Financial and Non-Financial Interests in Human Research Disclosure: IRB Members and Staff
- 500 CH.1 Determining Financial and Non-Financial Interests Related to Human Research
- Yale University Policy on Conflict of Interest and Conflict of Commitment
<http://www.yale.edu/provost/html/coi.html>

Contacts

Subject	Contact	Phone
Submitting protocol-specific conflicts of interest (Biomedical Research)	Human Investigation Committee	203.785.4688 ysmhic@yale.edu
Submitting protocol-specific conflicts of interest (Social, Educational and Behavioral Research)	Human Subjects Committee	203.785-4688 human.subjects@yale.edu
University requirements (annual and other) regarding disclosure of interests and commitment)	Conflict of Interest Office	203-785-4780 conflicts@yale.edu

Roles and Responsibilities

[Human Research Protection Program](#)

The Human Research Protection Program provides an integrated institutional system of to adhere to the highest ethical standards of protection of human research participants, and to identify and implement means for ensuring these protections.

Human Investigation Committee

The HIC I, HIC II, HIC III and HIC IV serve as the Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

Human Subjects Committee

The HSC is responsible for the review and oversight of social and behavioral research involving human subjects.

Yale Provost's Conflict of Interest and Conflict of Commitment Committee

A Committee composed of faculty and staff, who are appointed by the Yale Provost to review conflict of interest and conflict of commitment disclosures that are submitted annually by faculty and staff. The Committee determines whether an actual conflict of interest exists, and, if so, by what means the interest can be eliminated or managed.

References:

Food and Drug Administration Regulation 21 CFR 54 and Guidance: <http://www.fda.gov/default.htm>

Public Health Services Regulation 42 CFR 50.603; 45 CFR 94.3

NSF Award and Administration Guide, IV.A

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Revision History

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