
Yale University Human Research Protection Program

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

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Scope

This policy applies to all members of the Yale University research community, who

- 1) serve as principal investigator or investigator on a human research protocol and are responsible for the design, conduct or reporting of a human research project, or who the principal investigator deems otherwise responsible or
- 2) are responsible for the oversight, review and approval of human 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

Faculty members who serve as principal investigators and investigators are required to carry out their responsibilities in a manner that avoids or minimizes any real or potential interest that may adversely affect the protection of research participants, the credibility of the research or the community's trust in Yale as a research institution.

Investigators must make known any financial interest or non-financial relationship or interest regarding any specific research project to the Principal Investigator and, in turn, the PI must disclose the name of the individual(s) with such interest or relationship to the IRB.

Additionally, persons who serve as a member of, or a consultant to, the IRB or are employed as IRB staff must disclose their protocol specific interest to the IRB Chair, Vice Chair or Director and cannot conduct protocol reviews or be physically present during the deliberations and voting associated with the protocol if they have a financial or other interest related to the protocol, except to provide information at the IRB's request.

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) and Public Health Services regulations 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 arises when there is a divergence between an individual's private interests, or the interests of the individual's immediate family, and his/her professional obligations to the research. Conflicts are common and frequently arise due to investments in, or the transfer of knowledge gained through, research and scholarship. Transference methods often include consulting and commercialization of technologies derived from the research. While it may be appropriate for a research team member or other person to be compensated for these extramural activities, it is never appropriate for the individual's action or decisions related to the research to be influenced by the possibility of personal gain.

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. Financial interests held by those conducting the research or the research's sponsor 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. Accordingly, there is a strong presumption against permitting any person with related significant financial interests to participate in the conduct of such research, particularly if the protocol involves more than minimal risk. Only in rare and compelling circumstances might an exception be made.

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

- 1) ensure that interests that have the potential to 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.

Financial Interest

1) Anything of monetary value (greater than \$0) including, but not limited to, salary, loans, gifts, royalties, or other payments for services, including honoraria, speaking fees, lectureship fees, study completion or enrollment bonuses or study outcomes awards made directly to research team members, payments for consulting services and services on advisory committees; 2) intellectual property rights, including patents, patent applications, copyrights, and royalties from such rights; 3) equity interests, e.g., owning or having the right or obligation to acquire stocks or stock options, partnership interests or other securities in a for-profit entity; 4) debt interests, e.g., bonds; and 5) a position as consultant, employee, director, or manager of an entity.

The term "Financial Interest" does NOT include: 1) Salary or other remuneration received from grants or contracts to Yale or Yale monies used to directly support the conduct of a specific research endeavor; 2) stock owned through mutual funds; 3) reimbursement for travel expenses; or 4) intellectual property rights developed in the course of employment at a previous or current employer that remain the exclusive property of that entity or that may be widely published and for which the individual may be pursuing patent interests provided that the interest is not associated with ongoing research.

Non-Financial Relationship or Interest

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 or Designee will seek to determine the ability of the parties to remain objective in light of the interests or relationships.

Immediate Family

Spouse, domestic partner or dependent children.

Significant Financial or Non-Financial Interest

A financial interest that exceeds \$10,000 or a non financial interest that is deemed significant by Yale University Policy on Conflict of Interest and Conflict of Commitment. Generally speaking, investigators with significant financial interests are prohibited from partaking in research pursuant to University policy, unless they can justify exceptional circumstances and rebut the presumption against allowing participation in the research..

Policy Sections

500.1 Disclosures of Protocol-Specific Interests

Investigators on a research team and/or their Chair or Section Chief, a member of, or a consultant to, a Yale IRB, and a member of the IRB staff will be considered to have a protocol-specific interest that must be disclosed to the IRB and the Principal Investigator as appropriate when the person or the person's immediate family

- a. has a relationship, financial or otherwise, with the protocol's sponsor that could be affected by protocol approval decisions or by the conduct of the research.
- b. has a financial interest or a non-financial interest in a competitor of the protocol's sponsor or in a competing drug or device under investigation in the protocol.
- c. has a financial interest or non-financial relationship with the manufacturer of any item being evaluated in the protocol, such as a drug, device, program, method, etc.
- d. has a management or fiduciary position (such as serving as an officer or director) with a protocol's sponsor
- e. serves as a consultant or scientific advisor to the protocol's sponsor or any organization or individual that could be affected by either a decision to approve or disapprove the protocol, or by the conduct of the research.
- f. is an inventor of any item investigated in the protocol, such as a drug, device, program, method, etc.

500.2 Persons Required to Disclose Individual and Institutional Protocol-Specific Interests

Research Personnel:

Individual protocol-specific conflicts of interest must be disclosed by the following individuals:

- Principal investigator and co-investigator(s) listed on a human research protocol application or a proposal, and
- Research team member(s) deemed otherwise responsible by the PI.

Department Chairs or Section Heads:

Yale University recognizes that Department Chairs or other persons responsible for supervising the Principal Investigator may be in a position to influence the conduct or outcome of the research. For that reason, such persons are required to make known a financial interest or non-financial relationship or interest regarding any specific research project to the Principal Investigator and disclose their interest to the IRB.

IRB Members, Staff and Consultants:

Conflicts of interest must be disclosed to the Chair or Vice Chair of the IRB or designee by the following individuals:

- a) IRB members, staff and consultants, and Director(s). If conflicted, such affected persons cannot take part in the discussion or voting of said project; and
- b) IRB Chairs/Vice Chairs and Designee assigned to review protocol- specific interests are required to disclose their interests to the University's Conflict of Interest and Conflict of Commitment Committee, and are prohibited from discussion and vote or conducting expedited review on a given project with which they are conflicted.

500.3 When to Disclose Protocol-Specific Interests

Investigators or other research personnel as identified in this policy, consultants and Department Chairs or Section Chiefs, must make known protocol-specific interests to the Principal Investigator and disclose the interests to the IRB at the time a new research protocol is being submitted to the IRB or when such an individual joins the research team. Protocol- specific interests must also be disclosed to the IRB when continuing review of the protocol is requested and when there is any actual or anticipated material change in related outside activities or financial interests related to the research. Disclosure is made by indicating the affected person(s) by name on the IRB protocol application form, the Form 5R for reapproval, or the personnel amendment request form.

500.4 Principal Investigator Review of Protocol-Specific Interests

In addition to disclosing financial interests or non-financial interests or relationships to the IRB, research personnel as defined in this policy and Department heads or Section Chiefs responsible for supervising the Principal Investigator must make known protocol-specific interests to the Principal Investigator.

The Principal Investigator is responsible for reviewing the interest to determine whether or not the interest may adversely affect the rights or welfare of research volunteers or the integrity of the research. The Principal Investigator should consider whether or not the interest must be a) minimized or eliminated and/or b) disclosed during the informed consent process to provide the

research participants with the facts necessary to make a knowledgeable and sound decision as to whether or not they wish to participate in the study.

The Principal Investigator is encouraged to consult with the IRB regarding how and when protocol-specific interests can be managed, reduced or eliminated and must inform the IRB of the actions taken to minimize or eliminate the conflict of interest. The Principal Investigator should also report to the IRB any incidents where he/she is feeling pressure or influence from colleagues, department chairs or others not to manage the protocol-specific interest.

The IRB is responsible for reviewing the actions taken by the Principal Investigator. The IRB is the final authority in determining whether or not the research, with the conflict of interest and its management plan, can be approved so that the interests of human research participants can be protected.

500.5 IRB Review of Protocol-Specific Interests

Research Personnel and Protocol Specific Interests:

Protocol-specific financial interests or non-financial interests or relationships that are disclosed to the IRB will be reviewed by an IRB Chair or Vice Chair. The IRB Chair or Vice Chair may appoint a duly qualified person to serve as designee. The Chair/Vice Chair or designee is responsible for reviewing the interest to determine whether or not the interest may adversely affect the rights or welfare of research volunteers or the research integrity.

The Chair/Vice Chair or designee will determine whether or not an interest that is identified as having the potential to adversely affect the rights or welfare of research volunteers or the integrity of the research must be reviewed by a fully convened IRB or via an expedited manner. The fully convened IRB, the Chair/Vice Chair or designee is responsible for determining when such an interest must be managed, reduced or eliminated.

Conflict of Interest management plans or requests by the IRB, the Chair/Vice Chair/Designee to manage, reduce or eliminate conflicts of interest that are performed during an expedited review will be shared with the fully convened IRB at the discretion of the IRB Chair.

Conflict of interest management plans and requests to reduce or eliminate an interest are communicated to the Provost's Committee on Conflict of Interest and Conflict of Commitment (COIC).

When appropriate, the IRB may defer a decision related to a protocol-specific conflict of interest until the COIC has had the opportunity to review the conflict and aid in the decision making. In all instances, the decision that provides the most stringent protection to human research participants will be the one implemented.

The IRB or the Chair/Vice Chair/Designee may at any time require that a protocol-specific interest be disclosed during the informed consent process to provide research participants with the facts necessary to make a knowledgeable and sound decision as to whether they wish to participate in the study. When such a disclosure is required, it will not be considered a management of the interest.

IRB Members, Staff and Consultants:

The IRB Chair or Director will review relevant information regarding the actual or potential protocol-specific interests of IRB members, staff and consultants who take part in the deliberations and decisions concerning the approval of human research protocols. Such review will take place prior to the individual being assigned as a primary reviewer, expedited reviewer or

consultant for a protocol, or the individual participating in the consideration or approval of protocol submissions.

500.6 Significant Financial Interests and Institutional Review Board Approval

There is a strong presumption against permitting a Principal Investigator or other person as defined in this policy with related significant financial interests to participate in the conduct of such research, particularly if the protocol involves more than minimal risk. Only in rare and compelling circumstances might an exception be made.

Additionally, per University policy, there is a strong presumption against the IRB approving research when it is funded by a startup company in which the research member proposing the research has an equity interest, or a non-equity financial interest of over \$10,000 in a year (whether derived from consulting fees, honoraria, royalties or some other manner), or serves as a member of the company's Board. (See Yale University Policy on Conflict of Interest and Conflict of Commitment <http://www.yale.edu/provost/html/coi.html>)

IRB members, staff and consultants, IRB Chair(s) or Directors and other such persons cannot take part in the discussion or voting on a research project in which they have an interest. Persons with protocol-specific interests will be required to physically remove themselves from convened meetings during the deliberation and voting of the protocol submission.

Related Information

500 PR1: Member/Consultant Disclosure Procedures

500 PR2: Investigator/Research Team Member Disclosure of Protocol-Specific Interests to the IRB

500 PR3: IRB Review 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 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 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 apparent or actual conflict of interest exists, and, if so, by what means the interest can be eliminated or managed.

References:

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Investigator Conflicts of Interest and Review; Stanford University
<http://humansubjects.stanford.edu/hrpp/manual.html>

Investigator Conflicts of Interest and Review; University of California San Francisco
http://www.research.ucsf.edu/CHR/Guide/chrCOI_CHR.asp

Kim, S.Y.H., R. W. Millard, P. Nisbet, C. Cox and E.D. Caine, Potential research participant's views regarding researcher and institutional financial conflicts of interest, *J Med Ethics*, 2004; 30:73-79.

National Institutes of Health, Conference on Human Subject Protection and Financial Conflicts of Interest, *Transcript*, August 2000

Pharmaceutical Research and Manufacturers of America. PhRMA Code on Interactions with Healthcare Professionals. Wash D.C., PhRMA, 2002.

Public Health Services Regulation 42 CFR 50.603

U.S. General Accounting Office, *Report to the Ranking Minority Member, Subcommittee on Public Health, Committee on Health, Education, Labor and Pensions, U.S. Senate*, November 2001

Weinfurt, Kevin, PhD, Joëlle Y Friedman MPA, Jennifer S Allsbrook BSPH, Michaela A Dinan BS, Mark A Hall JD, Jeremy Sugarman MD, MPH, MA, *Views of Potential Research Participants on Financial Conflicts of Interest: Barriers and Opportunities for Effective Disclosure* , *Journal of General Internal Medicine* 21 (9), 901–906.

Yale University Faculty Handbook, Section X. University Policies Concerning Teaching and Research (http://www.yale.edu/provost/handbook/handbook_x__university_policies_concerni.html)

Yale University Policy on Conflict of Interest and Conflict of Commitment
<http://www.yale.edu/provost/html/coi.html>

Revision History

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