Examples of Significant External Relationships

The following financial interests and external relationships of the University or its leaders may create a Significant External Relationship (SER) when they reasonably appear to be related to human subjects research. The Institutional Conflict of Interest Committee (ICOIC) shall establish criteria for identifying SERs and referring them to the ICOIC:

- University representation (*qua University*) on boards of directors of external for-profit entities;
- Inter-institutional relationships (collaborations, alliances, etc.) with commercial entities;
- License of University technology (inclusive of royalties and other related payments) through the Office of Cooperative Research (OCR);
- An equity interest in a Yale start-up company
- Grants or donations from a commercial entity
- Donations to the University of significant magnitude when the donor has a business interest in the outcomes of Yale human subjects research.
- Significant Financial Interests (as defined in Yale’s COI Policy) of University Leaders
- Other financial interests or external relationships of the University that the University Conflict of Interest Committee (COIC) determines may create a potential ICOI.

Evaluation of SERs

The ICOIC will obtain information as needed from University offices and/or individuals regarding SERs, including, for example, gifts to the University, Yale equity interests, licensing/patent or royalty rights held by Yale, and instances when a Yale employee or faculty member serves on a Board of Directors or has fiduciary responsibility related to a commercial entity with ties to the University.

Review of Potential Institutional Conflict of Interest

Where an SER or other institutional interest has been identified that may constitute an ICOI in Human Research, the ICOIC will develop a plan for managing the conflict. The ICOIC may discuss the matter with the individuals involved in the SER, with representatives of Yale’s human research protection programs, and with those who would be involved with managing the conflict. Whenever possible, the ICOIC will structure a management plan that permits human subjects research to be carried out with appropriate safeguards, such as use of an external IRB. The ICOIC will report its findings to the President, to the Chair of the cognizant IRB, and to the Director of the HRPP. The HRPP and the cognizant IRB may impose additional requirements on any human subjects research that they perceive might be influenced by the SER.
In determining whether an ICOI exists that should be managed, the following factors will be evaluated:

- The level of risk to the human subjects in the research,
- The level of risk to the integrity and objectivity of the research
- The level and type of the financial interest or relationship held by the institution
- How direct and immediate an institutional leader’s authority is over the research and the people involved in the conduct of the research
- Whether the University is uniquely qualified, by virtue of distinctive resources (e.g. special facilities or equipment, unique patient populations) and the experience and expertise of its investigators, to conduct the research and appropriately safeguard the welfare of the human research participants involved
- Whether a practical and effective plan for assuring the integrity of the human research participants can be implemented
- The risk of inhibiting the academic freedom of the researcher who has proposed the affected research
- Whether the relationship may inappropriately influence the direction or scope of future University human subjects research, and
- The perceived risk to the reputation of the University and the researchers.

In each case where an ICOI involving human research participants is identified, the ICOI Committee for Evaluating ICOIs, in consultation with the Human Research Protection Program (HRPP), will assess the relationships between the SER and the research and recommend steps to protect and inform human subjects appropriately. The plan may include one or more of the following:

- Referral of IRB review of the research or category of research to an external, independent IRB
- Disclosure of the significant external relationship in participant consent forms or recruitment materials
- Disclosure of the significant external relationship in relevant publications/presentations
- Disclosure of the significant external relationship to research sponsors
- Establishment of an independent monitoring process to ensure that the ICOI does not undermine the integrity of the research
- Disqualification of certain University personnel from participation in the research
- Permitting only certain procedures and/or analysis to occur at Yale
- In extreme cases, prohibiting the research from being conducted at Yale
- Reducing the financial interest (e.g., equity or royalty) involved in the ICOI
- Other mechanism(s) as determined by the ICOIC in consultation with the HRPP.

In addition to any action(s) that the ICOIC mandates, documentation of the management plan will also include identification of the nature of the conflict, and any risk(s) to human research participants.

Institutional Conflict of Interest Committee (ICOIC)

A committee appointed by the President and charged with the review of SERs and LSFIs to assess whether they present institutional conflicts of interest in human research. If the ICOIC determines that an ICOI exists in relation to human subjects research, it will decide upon actions to eliminate or manage the
ICOI, and it will report the ICOI along with those decisions to the President and Human Research Protections Program (“HRPP”).

The President shall appoint a chair of the ICOIC from among its members. The Committee shall include the following: one or more tenured faculty not associated with the HRPP or the University Conflict of Interest Committee (COIC), a cognizant Deputy Provost, the Associate Vice President for Research Administration, the Chair of the COIC, a University IRB Chair, and an IRB community member. The Director of the HRPP and the Director of the Conflict of Interest Office will staff the committee and a representative of the Office of General Counsel will serve in an advisory capacity to the Committee.

Relationship of ICOIC to IRB in ICOI Management

Institutional conflicts of interest are managed in a complementary manner by the ICOIC and the IRB.

The IRB mandates management plans for institutional conflict of interest in human subjects protocols from the perspective of protection of human research participants.

Compliance

Researchers are required to comply with all management plans that have been implemented by the ICOIC and the IRB. Should a researcher disagree with the management plan recommended to the Provost or President, s/he may appeal the recommendations by following the process outlined in the University’s Conflict of Interest Policy.

References

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

HRPP Policy 501 Institutional Conflicts of Interest in Human Research

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

500 PR1: Procedures for Disclosing Financial and Non-Financial Interests Related to Research


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