
Yale University Human Research Protection Program

HRPP Policy 501 Institutional Conflicts of Interest In Human Research

Responsible Office	Office of Research Administration	Effective Date	4/1/13
Responsible Official	Institutional Official	Last Revised	

Scope

This policy describes the University statement of principles regarding institutional conflicts of interest that may affect the protection of participants in human subjects research conducted at Yale.

Policy Statement

Yale University is committed to the expansion of knowledge through research and to the translation of its research results to benefit society. In support of its mission, the University, from time to time, enters into financial agreements with external entities. These relationships provide support to the University's research activities, facilitate the dissemination of knowledge, and enable the translation of discoveries into socially useful technology.

The University is also committed to ensuring the objectivity, independence, credibility and integrity of its research and the rigorous protection of the rights and well-being of humans who participate as research subjects. University functions are generally designed to separate the specifics of the institution's financial relationships with external entities and donors from the research process and from the administrative oversight of the research. However, certain relationships between the University and external entities ("Significant External Relationships," or "SERs") carry the potential to compromise the objectivity and/or independence of the review and/or conduct of human subjects research performed at Yale, thereby posing the risk of creating Institutional Conflicts of Interest (ICOLs). Additionally, University Leaders may have personal significant financial interests that create an incentive to bias their institutional decision-making pertaining to human subjects research and oversight, thereby posing the risk of creating ICOLs.

The fundamental premise of this policy is that the University has an obligation to act, through its authorized leaders, in the best interest and in furtherance of its core mission and values, and must not let external relationships or financial interests interfere with that obligation. Accordingly, the University is committed to identifying and addressing potential, actual and perceived ICOLs in order to safeguard its human subjects research and human subjects research oversight processes.

The Institutional Conflict of Interest Committee (ICOLC) is responsible for the implementation of this policy. The ICOLC establishes and oversees procedures to collect information relating to SERs and relevant significant financial interests of University leaders (LSFIs). Additionally, any individual employed by the University or engaged in the review or conduct of University research who becomes aware of an SER is obligated to bring it to the attention of the ICOLC, or to the attention of the Institutional Official (IO) or an Institutional Review Board (IRB) Chair, who will in turn forward it to the ICOLC. The ICOLC reviews SERs and LSFIs to determine whether they pose the risk of creating ICOLs. If the ICOLC determines that a risk of ICOL exists in relation to human subjects research, it will decide upon actions to eliminate or manage the ICOL, and it will report the ICOL along with those decisions to the Human Research Protections Program ("HRPP"). The HRPP and the IRBs may conduct additional reviews specific to human subjects research and may impose measures, in addition to those determined by the ICOLC, to protect human research subjects and ensure the integrity of research.

Definitions

Human Research Protection Program (HRPP)

The Human Research Protection Program is responsible for the oversight of human research protection through ongoing education, monitoring and evaluation of all parties involved in conduct of human research. Yale's Institutional Review Boards (IRBs) function under the auspices of the HRPP.

Human Subjects Research

For purposes of this policy, any research that requires review and approval of the Yale Institutional Review Boards, pursuant to Yale policies and procedures.

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.

Institutional Conflict of Interest in Human Research

A significant external relationship that creates the opportunity and incentive to directly and significantly bias decision-making or compromise the professional judgment of the IRB, the HRPP, the researchers, or others in the conduct, review, or oversight of human subjects research.

Institutional Review Board

A University committee established in accordance with 45 CFR §46 that is designated by the University to protect the rights and welfare of subjects who participate in research.

Leadership Significant Financial Interest (LSFI) in Human Research

An interest deemed to be significant by the applicable governing policy. For example, faculty and faculty administrators' financial interest disclosures are governed by the University's Policy on Conflict of Interest. Senior non-academic administrators are subject to a financial interest disclosure process overseen by the University's Office of General Counsel. Financial interest disclosures of members of the Yale Corporation and Officers of the University are governed by Yale Corporation policy.

University Leaders

Members of the Yale Corporation, Officers of the University, senior non-faculty administrators, faculty administrators, and members of research compliance committees.

Significant External Relationship

A relationship with an outside entity held by a senior official of the University, or a University relationship with an individual or commercial entity that may reasonably create an incentive to bias decision-making regarding University human subjects research. (See Procedure 501 PR101.)

Examples of Significant External Relationships:

Startup Companies

“Startup” companies are relatively newly formed, privately held, for-profit companies that may be based on intellectual property developed by an individual at Yale and provide the opportunity for the development and commercialization of Yale inventions. Yale’s startup policy (Conflict of Interest Policy, Appendix C) includes several significant restrictions on such SERs, including: Yale discourages the use of Yale space by startup ventures; and a startup company may only use Yale equipment or laboratories subject to a written agreement with the University and with strict limitations as to time and extent and only after review and approval by the Provost.

Publicly and Non-publicly Traded Equity

When Yale licenses technology or other intellectual property, it may acquire an equity interest in a company or an entitlement to equity (including options or warrants) in a company that is or may become the sponsor of human subjects research at Yale or is the manufacturer or distributor of a product that is studied or tested in human subjects research at Yale.

Gifts

Gifts to the University may create SERs if the donor is also sponsoring or offering to sponsor human research in which the donor has an interest. The ICOIC will establish criteria elaborating on the criteria for when a gift is an SER, including, for example, when the donor

1. is the manufacturer or distributor of a product that is either studied or tested in the research at the University or based at least in part on technology developed at Yale; or
2. Is the holder of an Investigational New Drug (IND) or Investigational New Device (IDE) approval for the research to be sponsored at Yale.

The ICOIC will establish criteria for when a gift is of sufficient magnitude that it might influence human research or its oversight, and therefore constitute an SER.

Note: University Equity Holdings

The University’s Investment Office’s information and decision-making related to Yale assets are independent of those involved in the operations of the University and in the conduct and oversight of research. Its holdings and investment decisions are confidential and therefore do not create a risk of institutional conflict of interest. They are therefore not subject to disclosure or management under this policy.

Significant Financial Interests of University Leaders:

All University Leaders are required to disclose their outside activities and financial interests at least annually. These disclosures are submitted to and reviewed by various officials or bodies, depending on the position of the University Leader, e.g., University Officers’ disclosures are reviewed by the President

and Corporation, deans' disclosures are reviewed by the President, senior non-faculty administrators' disclosures are reviewed by the Vice President and General Counsel. These various reviewers will determine if University leaders' disclosed interests pose the risk of creating ICOIs that would bias their institutional decision-making pertaining to human subjects research and oversight and, if so, will forward relevant information to the ICOIC for further review and action.

Related Information

501 PR 1 Procedures for Identification and Review of Institutional Conflicts of Interest Related to 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 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