
Overview
This procedure identifies the process whereby the Principal Investigator and the Institutional Review Board (IRB) review the disclosures of financial and non-financial interests required by University Policy and HRPP Policy 500: Disclosures and Management of Interests In Human Research, and evaluates whether or not the disclosed interest(s) poses a potential to affect the protection of human research participants.

Definition
Responsible Person: Faculty, staff and students who serve as members of a research reviewing committee, or who 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.

Principal Investigator Review of Protocol-Specific Interests
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. The Principal Investigator 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.
Checking Annual Researcher Disclosure to Identify Potential Protocol-Specific Conflicts of Interest

The IRB is responsible for reviewing whether or not the interests disclosed by the Responsible Person on the annual University disclosure form affect the protection of human research participants, the integrity of the research, or the study outcome. The review by the IRB is performed at the time the regulatory review of an initial protocol is conducted, and when a request for continuing review or an amendment adding a Responsible Person to a protocol is submitted to the IRB.

The IRB uses the COI-Coeus Data Report and the Case Status Report to conduct the review.

IRB staff search by protocol number or by individual name to view the status of a Responsible Person’s disclosure. The staff review the Disclosure Date, Case Status and Intellectual Property(IP) fields.

When the Case Status of the Principal Investigator (PI) is Required, No Disclosure or Expired, then the IRB will reject the submission and notify the PI that the submission cannot be processed by the IRB until such time that the PI has filed or updated his/her annual disclosure with the COI office.

When the Case Status of the PI is Pending, the IRB Office will contact the COI Office to determine whether or not the processing of the IRB Submission can move forward.

When the Case Status of Responsible Persons other than the PI is Required, No Disclosure or Expired, then the IRB will conduct the Regulatory Review process on initial protocol submission, or other requests for protocol review (e.g., continuing review or amendment). However, correspondence back to the PI, either requesting changes due to the Regulatory Review process or in notices either requiring revision or granting approval, will indicate that the Responsible Person in question has been removed from the protocol and is unable to participate in the research until such time that the annual disclosure is on file. The correspondence will note that an amendment to add the individual back to the research team will be required if the submission is approved before the individual has complied with the requirement to file his/her annual disclosure.

A Case Status of AAN (All Answers No) requires no further action by the IRB. A Case Status of No SFI (No Significant Financial Interest) also requires no further action by the IRB unless the record also indicates that IP is held. In that case, further review in the InfoEd COI database is required to determine the relatedness of the IP to the research described in the protocol.

When the Case Status of the PI or any Responsible Person is Transactional Review, further review in the InfoEd COI database is required because an SFI has been disclosed.

The IRB staff member will notify the University’s Conflict of Interest Office when the name of the PI or any Responsible Person cannot be found in the COI-Coeus Data Report. The Conflict of Interest Office is responsible for entering the name of the person into the appropriate database(s).

The IRB reviewer will review the Details or Comments field of the most recent disclosure submission in the InfoEd COI database and evaluate whether or not the interest justifying the Transactional Review or the Intellectual Property is related to the specific protocol. If not, no further action is required. If related, the interest is passed to the IRB Chair or appointed designee. The Chair/designee is responsible for reviewing the interest and validating relatedness. The Checklist (500 CH1) Determining Financial and Non Financial Interests Related to Human Research is used to evaluate and identify the interest.

IRB Review of Protocol-Specific Interests

Research Personnel and Protocol Specific Interests:

Protocol-specific significant 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 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 accessible to the fully convened IRB.

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.

The plan is communicated to the Principal Investigator by the IRB and is provided to the University’s Conflict of Interest and Conflict of Commitment Committee (COIC) by providing the plan and supporting documents to the COIC for uploading into InfoEd. The COIC must review and approve the plan in accordance with its operational procedures.

**IRB Members, Staff and Consultants:**

The IRB Chair, Director or designee will review relevant information regarding the 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. IRB members, staff or consultants with a conflict of interest may be present at the meeting to answer questions regarding the protocol, if necessary, but may not be present during Committee deliberation or voting.

**Privately Held Entities**

Additionally, in accordance with University policy, research that is proposed to be sponsored by a privately held entity in which the faculty member who would conduct such research has an equity interest or Board seat or other significant financial interest must be reviewed and approved in advance by the Provost’s Committee on Conflict of Interest (COIC).

**IRB Documentation of Conflict of Interest**

Meeting minutes will document those instances in which an IRB member, staff person or consultant has left the meeting due to a conflict of interest. Such documentation will include the name of conflicted person and the fact that their absence from that part of the meeting was due to their conflict.

**References:**

Public Health Services Regulation 42 CFR 50.603; 45 CFR 94.3

Food and Drug Administration Regulation 21 CFR 54 and Guidance: [http://www.fda.gov/default.htm](http://www.fda.gov/default.htm)

NSF Award and Administration Guide, IV.A

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

Revision History
Procedure issued 11/19/09. Revised 7/28/10, 8/24/12