
Yale University Human Research Protection Program

500 PR.3 IRB Review of Financial and Non Financial Interests Related to Human Research Projects

Overview

This procedure identifies the process whereby the Institutional Review Board (IRB) reviews 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: An individual responsible for the design, conduct or reporting of a human research project. For purposes of this procedure, these persons include principal investigators, co-investigators, and other research team members identified by the principal investigator as responsible .

Checking Annual Disclosure to Identify Potential Protocol-Specific Conflicts of Interest

University policy requires that individuals considered Responsible Persons disclose their extramural activities and financial interests at least annually with the University's Conflict of Interest Office. The IRB is responsible for reviewing whether or not the disclosures filed by Responsible Persons pose a potential to affect the protection of human research participants, the integrity of the research, or the study outcome. If so, then the IRB is responsible for requiring additional safeguards to ensure participants' protection and/or study integrity in accordance with 45 CFR 46.111 or 21 CFR 56.111. 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** to conduct the review.

IRB staff will search by protocol number or by individual name to view the status of a Responsible Person's disclosure. The staff should review the **Disclosure Date** and **Case Status**.

A Case Status of **No SFI** (No Significant Financial Interest) or **AAN** (All Answers No) requires no further action by the IRB.

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 submissions, 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, must 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 should 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.

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

The IRB staff member should 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** is related to the specific protocol. If not, then no further action is required. If related, then 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 (550 CH1) *Determining Financial and Non Financial Interests Related to Human Research* is used to evaluate and identify the interest.

The IRB Chair or designee is responsible for drafting a plan to reduce, eliminate or manage the potential effect posed by the interest. The IRB Chair or designee can consult with the COI Office when necessary. The draft plan is reviewed, amended and voted on by the fully convened IRB in accordance with (500 PR.2) *Procedures for Disclosing Financial and Non Financial Interests Related to Specific Human Research Projects: Research Team Members and Departmental Chairs*.

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.

Exceptions:

This procedure does not apply to unfunded projects or projects with no commercialization potential. Examples may include research where the study poses minimal risk to research participants and is 1) Social, Behavioral or Educational in nature, 2) medical record research and aims to gain understanding of health care assessments or treatments, and 3) studies deemed by the IRB to be exempt or not human subjects research.

References:

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

Yale University 500 FR 2: Financial and Non Financial Interests in Human Research Disclosure: Researchers and Department Chairs

500 CH.1: Determining Financial and Non Financial Interests Related to Human Research

500 PR.2: Procedures for Disclosing Financial and Non Financial Interests Related to Specific Human Research Projects: Research Team Members and Departmental Chairs

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