
Yale University Human Research Protection Program

500 PR.1 Procedures for Disclosing Financial and Non Financial Interests Related to Research

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Overview

This procedure describes who must disclose financial and non-financial interests as per HRPP Policy 500 related to human research, to whom and when the disclosure is made. The procedure is designed to help ensure that mechanisms are in place to ensure that the review and approval of human research is conducted objectively, without undue influence or bias.

Federal regulations (45 CFR § 46.107; 21 CFR § 56.107) and [Yale policy](#) stipulate that the IRB is responsible for ensuring that human research is considered and conducted in a manner that protects the rights and welfare of the research participants. In order to fulfill this obligation the IRB must be knowledgeable of interests related to research that may knowingly or involuntarily compromise the review process or the rights of human subjects.

Persons Required to Disclose

Research Personnel

Research personnel who are responsible for the design, conduct or reporting of a human research project must disclose individual protocol-specific conflicts of interest to the Principal Investigator. The Principal Investigator must inform the IRB of those research personnel who have protocol-specific conflicts, by naming the affected individual on the IRB protocol application. 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.

Department Chairs or Section Chiefs

Yale University recognizes that Department Chairs, Section Chiefs 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 any individual or institutional financial interest or non-financial relationship or interest regarding any specific research project to the Principal Investigator and must disclose that interest to the IRB on the IRB application.

IRB Chairs and Vice Chairs

IRB Chairs and Vice Chairs are required to disclose annually to the University's Conflict of Interest and Conflict of Commitment Committee all interests as required by University policy, and are also required to complete the annual IRB-specific disclosure form (500 FR 1). Updates to the disclosure should be made whenever new interests are accrued.

IRB Members

IRB members who are Yale faculty or staff are required to comply with the University Conflict of Interest annual disclosure requirements. In addition, all IRB members are required to disclose annually to the IRB

Chair(s) or designee any current real and potential interests that are related to the research which is reviewed by the Yale IRB by completing the annual IRB-specific disclosure form (500 FR 1), and must update the disclosure information whenever a new interest is acquired that affects or has the potential to affect his/her obligations to review research protocols or related documents.

Staff

IRB staff who are not IRB members and who review human research protocols or have input into IRB review of protocols are required to disclose annually to the IRB Chair(s) or designee any current real and potential interests that are related to the research which is reviewed by the Yale IRB by completing the annual IRB-specific disclosure form (500 FR 1) and must update the disclosure information whenever a new interest is acquired that affects or has the potential to affect his/her obligations to review research protocols or related documents.

Consultants

Consultants active on the research protocol are responsible for reporting to the Principal Investigator. Consultants to the IRB are responsible for reporting conflicts to the IRB Chair/Vice Chair, designee or Committee any interests related to a specific research protocol. Such disclosure will be documented in the Committee minutes or regulatory review form if the review is done in an expedited manner.

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, the HSC Request for Renewal, or the personnel amendment request form.

IRB members must notify the IRB staff of any protocol-related conflict of interest (including serving as a member of a research team for a protocol under IRB review, having a financial interest in the research with value that cannot readily be determined, or having any interest that the member believes conflicts with his/her ability to objectively review a protocol) at the time they are assigned as primary or secondary reviewer for a protocol, and must notify the Chair or Vice Chair prior to a protocol being discussed at the IRB meeting.

IRB staff who are not members but provide regulatory review of protocols must notify their supervisor at assignment of regulatory review. IRB staff who are not members but may have input into IRB review of protocols must notify the Chair or Vice Chair prior to any full board discussion of the protocol or expedited review.

Consultants to the research protocol must make known protocol-specific interests to the Principal Investigator at the time of protocol submission. Consultants to the IRB will be queried by the IRB Chair as to whether they have any protocol-related conflicts and must make disclosure to the IRB Chair, Vice Chair, designee or Committee prior to their providing review services for the protocol.

References

Public Health Services Regulation 42 CFR 50.603; 45 CFR 94.3

Food and Drug Administration Regulation 21 CFR 54.2 and Guidance: <http://www.fda.gov/default.htm>

NSF Award and Administration Guide, IV.A

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

<http://www.yale.edu/provost/html/coi.html>

Revision History

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