
Yale University Human Research Protection Program

500 PR.1 Procedures for Disclosing Financial and Non Financial Interests Related to Research: IRB Members, Staff and Consultants

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Overview

This procedure describes the disclosure process for reporting financial and non financial interests related to human research that is required of all persons serving as members and staff to the Yale Institutional Review Boards (IRB). This procedure also describes the disclosure process for persons serving as consultants to the IRBs. 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 influence or bias.

Federal regulations 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. Once known, the IRB review and approval process must be insulated from the potential conflict.

Disclosure to the IRB and Evaluation of Interests

IRB Members and Staff

IRB members and IRB staff who review human research 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. Additionally, the IRB member or staff person 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 in accordance with University IRB and Human Research Protection Program (HRPP) policies. The IRB Member and Staff Disclosure of Financial and Non Financial Interests Form (500 FR.1) is used to perform the disclosure.

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. Updates to the disclosure should be made whenever new interests are accrued.

Consultants

Consultants will be asked to disclose to the IRB Chair/Vice Chair or designee any interests related to a specific research protocol prior to their providing review services for the protocol.

Evaluations of Disclosures

The IRB Chair/Vice Chair or designee is responsible for evaluating all disclosures of interest and, when necessary, discussing the interest with the IRB member, staff person or consultant to evaluate the individual's ability to take part in protocol review and approval activities. The IRB Chair or designee will further evaluate the interest and determine whether or not the interest presents a conflict of a magnitude or type that could be perceived to influence, either consciously or not, the individual's objectivity in reviewing the research. When a conflict of interest is deemed to have the potential to impact the

individual's review responsibilities, the individual will be directed by the Chair or designee to recuse him/herself from IRB deliberations, reviews or decisions related to a research project for which a real or potential conflict has been identified. During a meeting of the fully convened IRB, a member recuses him/herself by physically leaving the room where the meeting is taking place.

The Chair, Vice Chair, or designee, at his/her discretion, will report the member and his/her protocol-specific interest and the directive to recuse from review and consult with the Provost's Committee on Conflict of Interest and Conflict of Commitment (COIC) regarding further COI management actions when appropriate.

Consultants will ordinarily not be permitted to serve as a consultant when in the opinion of the Chair/Vice Chair or designee an interest is disclosed that has the potential to influence the review and/or approval of a research protocol. A consultant who discloses an interest, but who is permitted by the Chair/Vice Chair or designee to serve as a consultant must disclose his/her interest to the full convened IRB prior to presenting his/her review findings.

Recusal from IRB Review and Minutes

No regular or alternate IRB member, staff or consultant may participate in the review or evaluation of a human research protocol after being directed by the Chair that he/she must recuse him/herself from participating in the review of and voting on the research. IRB members and staff are expected to self-identify any real or potential conflicting interests with any protocol submission or other item scheduled for review by the member or staff as noted in the Committee schedules and agendas.

Members cannot serve as a primary or secondary reviewer for a protocol submission in which they have a conflicting interest and have been directed by the IRB Chair/Vice Chair or designee to recuse him/herself. The member must notify the IRB Coordinator so that arrangements can be made to re-assign the reviewer responsibilities should this occur. Additionally such members and staff cannot participate in any other IRB review or activity in which they have conflicting interests, such as performing expedited review, reviewing adverse events or unanticipated problems involving risks to participants or others, exemption determinations or other activities that might be affected or appear to be affected by their objectivity in reviewing the study.

At the start of each IRB meeting, the IRB Chair will remind IRB members and staff to identify any conflict of interest they may have with a protocol submission. IRB members and staff will be further reminded to recuse themselves from any IRB deliberations or decisions concerning all protocol submissions in which they have, or appear to have, a conflict of interest.

Members/staff directed by the Chair to recuse themselves or who choose to recuse themselves must leave the meeting room during the deliberations and voting. However, at the discretion of the IRB Chair, members/staff may provide information and answer questions regarding the research prior to the recusal and deliberations of and voting by Committee members. The IRB minutes will document the name of the IRB member with the conflict and will document that the IRB member left the room during the discussion of the protocol and the vote. The recused member will not be counted toward quorum.

IRB members will be informed of a conflict of interest when the IRB relies on the expertise of a consultant who has a conflict of interest in the research as defined by the IRB Chair. Disclosure of said interest will be made prior to the consultant presenting the research protocol to the IRB and noted in the minutes.

IRB members and staff may volunteer to recuse themselves from the IRB discussion and/or vote when in the member/staff's opinion he/she cannot be objective about the research, so as to avoid the appearance of a conflict of interest.

Education and Training in COI

IRB members and staff are required to participate in education and training activities related to protocol-specific and other conflict of interest issues. Such activities may include online tutorials, attendance at IRB Policy Meetings, participation in topical workshops, and review and discussion of relevant literature distributed at IRB meetings.

References

45 CFR 46.107(e)

21 CFR 56.107(e)

Accreditation Council for Continuing Medical Education Report on Standards for Commercial Support accessed March 12, 2005 at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

American Medical Association. Opinion of the Council on Ethical and Judicial Affairs, E-8.061 <http://www.ama-assn.org/ama/pub/category/4001.html>> Accessed January 20, 2005.

Department of Health and Human Services, Office for Human Research Protections; Conflict of Interest Final Guidance <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>

Department of Health and Human Services, Office of Inspector General. OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Fed Regist 2003;68:23731-43.

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

FDA Information Sheets, FAQ, Section II, Question 12
(<http://www.fda.gov/oc/ohrt/IRBS/faqs.html#IRBMember>)

Yale University 500 FR 1: Financial and Non Financial Interests in Human Research Disclosure: IRB Members and Staff

Yale University HRPP Policy 500 Disclosures and Management of Personal Interests In Human Research
500 FR.1 Financial and Non Financial Interests in Human Research Disclosure: Yale IRB Members and Staff