Chapter 18
Financial Disclosure Requirements for Investigators, Research Staff, and IRB Members

Federal regulations at Title 21 Part 50 and Title 42 Part 50 of the Code of Federal Regulations (CFR) require the disclosure and management of financial Conflicts of Interest in research. The policies and procedures of Hospital for Special Surgery (HSS) for the disclosure and management of investigator Conflicts of Interest are fully delineated in separate HSS policies and procedures (including HSS’s Organizational Code of Ethical Behavior and Code of Conduct). They are summarized here for convenience. However, HSS’s policies and procedures should be consulted directly for definitive information about these requirements.

Federal human subject protection regulations at 21 CFR 56.107(e) and 45 CFR 46.107(e) require IRB members to be free of any Conflict of Interest. The policy of HSS’s Institutional Review Board for disclosure and management of IRB member Conflicts of Interest is set forth in Section IV below.

For purposes of this Chapter 18, a “Conflict of Interest” (or “COI”) includes any situation in which financial, professional, or personal interests or obligations may compromise, or could present the appearance of compromising, an individual’s or group’s professional judgment in conducting, reviewing, or reporting research.

I. Disclosure Requirements. Investigators and other personnel involved in the conduct or support of human subjects research (e.g., study planning and design, conduct of the study, data analysis, subject recruitment, subject consent, authorship, or the decision-making process related thereto) at HSS (including physician investigators and members of their research staff, whether or not employed by HSS) must disclose to HSS’s Conflicts of Interest Committee (the “COI Committee”) any “Financial Interest” (as defined in Section II below).

Conflict of Interest disclosures must be made prior to the submission of an application or proposal for external funding or at the time of application for IRB review, whichever comes first.

Thereafter, disclosure must be made (i) as new Financial Interests are obtained or as other changes in Financial Interests occur, and (ii) at least annually (typically in conjunction with the application for continuing review).

A current, up-to-date Investigator Financial Interest Disclosure Form from each of the investigators and other personnel involved in the conduct or support of human subjects research at HSS (including physician investigators and members of their research staff, whether or not employed by HSS) must be on file with the COI Committee before: (i) a
A proposal or application for external support can be submitted to the funding agency, organization, or sponsor; and (ii) any application for initial or continuing review can be processed.

For protocols submitted on the Exempt protocol application or the Expedited Retrospective Chart Review application, conflict of interest forms are not required unless specifically requested by the IRB.

II. Financial Interest Defined. All investigators and other personnel involved in the conduct or support of human subjects research at HSS (including physician investigators and members of their research staff, whether or not employed by HSS) must disclose to the COI Committee any Financial Interest in any human subjects research at HSS in the conduct or support of which they are involved (e.g., study planning and design, conduct of the study, data analysis, subject recruitment, subject consent, authorship).

“Financial Interest” means: (i) anything of monetary value that could reasonably appear to affect, or to be affected by, the research; or (ii) anything of monetary value in components whose interests could reasonably affect, or be affected by, the research. The latter includes, but is not limited to, membership in a partnership or group practice that could reasonably affect, or be affected by, the research. “Financial interest” also includes an option or a contractual or other right to acquire any of the foregoing.

“Financial Interest” includes interests held: (i) by (A) the investigator’s (or other research personnel’s) spouse, (B) the investigator’s (or other research personnel’s) parents, (C) all descendants of such person and his/her spouse, or (D) all descendants of such person’s parents and such person’s spouse’s parents; and (ii) through trusts or personal holding companies.

“Financial Interest” includes, but is not limited to, the following:

A. Compensation: Any compensation received in the past 12 months, or that is expected to be received over the next 12 months. This includes monetary compensation, such as salary and payments for services (e.g., consulting fees, honoraria, payments for services on advisory committees), as well as non-cash compensation (e.g., sponsored or reimbursed travel). For purposes of this Policy, an Investigator is not required to disclose travel that is sponsored or reimbursed by a federal, state, or local government agency, an Institution of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
B. Any Ownership Interest in a Public Company: Ownership of any stock or other equity, or the rights to acquire stock or equity (e.g., options or warrants), in a Public Company. This includes ownership interests held through trusts or personal holding companies. This does not include ownership of mutual funds or similar investments where the individual (or any member of such person’s Immediate Family, or any entity owned or controlled by any of them) has no control over the investments held by the fund.

C. Any Ownership Interest in a Non-Public Company: Any ownership of stock or other equity, or any rights to acquire stock or equity (e.g., options or warrants), the value of which cannot be readily determined through reference to public prices. This includes ownership interests held through trusts or personal holding companies. This does not include ownership of mutual funds or similar investments where the individual (or any member of such person’s Immediate Family, or any entity owned or controlled by any of them) has no control over the investments held by the fund.

D. Royalties from Intellectual Property: Any interest in a patent, trademark, copyright, or other intellectual property that currently produces or in the future may produce royalties or other payments to the Investigator.

E. Leadership Positions: Any position of leadership or influence. This includes being an officer, a member of the Board of Directors/Trustees/Managers, or a member of any advisory board.

However, Financial Interest does not include the following:

A. Salary, royalties, or other remuneration from HSS for purposes unrelated to the research in question;

B. Income from seminars, lectures, or teaching engagements sponsored by governmental agencies or non-profit organizations;

C. Income from service on advisory committees or review panels for governmental agencies or non-profit organizations; and

D. Funding to HSS for basic science research or other human subjects research on which the investigator is the principal investigator, or a sub-/co-investigator, by the company that sponsors the research in question or that designs, manufactures, markets, or sells any product (whether a drug, a device, or a biologic) that is part of the research in question.
III. **Conflict of Interest Procedures for Investigators.** The following describes the procedures that govern the operation of the Conflict of Interest process for investigators and research personnel performing or seeking to perform research at HSS:

A. **Receipt and Storage of Information.** The COI Committee will receive and review disclosures relating to the Financial Interests of investigators and research staff. The COI Committee recognizes that such information may be sensitive and highly confidential, and will treat such information in a confidential manner.

B. **Basis for Findings and Determinations.** The COI Committee will consider the information submitted on a case-by-case basis and render a decision as to whether the Financial Interest of the affected investigator or research staff person could reasonably affect the research activities, either directly or indirectly, or convey the appearance of such an effect. The COI Committee may consult with any source necessary to help in making its findings or determination or in the design, implementation, and monitoring of any mechanism or plan for managing Conflicts of Interest.

C. **Notification of Findings and Determinations.** If the COI Committee reaches a decision that no Financial Interest exists, the COI Committee will notify the IRB and the affected investigator or research staff person of that determination. If the COI Committee reaches a decision that a financial Conflict of Interest exists, the COI Committee will propose a management plan for the specific conflict for consideration, which may be approved or modified by majority vote of a convened quorum. Upon approval of a management plan by the COI Committee, the COI Committee will notify the affected individual of the proposed plan to manage the conflict.

D. **Requirement for Management Plans.** The COI Committee has complete discretion and authority in designing and approving a management plan. HSS’s Corporate Compliance Officer has complete discretion and authority in enforcing an approved management plan on behalf of HSS. Examples of management plans include, but are not limited to, the following:

   i. Public disclosure of Financial Interests;
   
   ii. Monitoring of the research by independent reviewers;
   
   iii. Modification of the research plan;
iv. Complete divestiture of Financial Interests in the company that sponsors the research or that designs, manufactures, markets, or sells any product (whether a drug, a device, or a biologic) that is part of the research;

v. Selection of another investigator or research staff person to perform the research or specified research-related functions (e.g., consenting of subjects; analysis of data);

vi. Disclosure of the conflicting interest in the informed consent document and any manuscripts or oral presentations based upon the research in question; and

vii. Severance of relationships that create actual or potential COI.

E. Approval and Implementation of Management Plans. The affected individual will be asked to acknowledge and agree to the terms of the proposed management plan for managing the COI. If the affected individual accepts the management plan, the COI Committee will notify the IRB of this outcome. If the affected individual does not agree to the terms of the proposed management plan, the research may not be initiated.

The management plan must be prospectively approved by both the COI Committee and by the IRB. The management plan must be in place before any research activities involving human subjects are initiated.

F. Disapproval. Disapproval by the COI Committee or the IRB constitutes disapproval by HSS, and the research may not be initiated.

G. Required Updates. Investigators and research staff must provide updates to the COI Committee and the IRB as soon as possible after any actual (or potential) COI is identified or acquired during the course of the research and for one year after its completion. In addition, investigators and research staff must provide updates to the COI Committee and the IRB at least annually (at the time of continuing review).

IV. Managing Conflicts of Interest in IRB Review of Research. The Office for Human Research Protections (OHRP) interprets the HHS regulations to prohibit IRB members from participating in the deliberative discussion or vote relative to any research in which they participate in any way, including study planning and design, conduct of the study, data analysis, subject recruitment, subject consent, and authorship. IRB members are likewise prohibited from participating in the deliberative discussion or vote relative to any research in which they have, or may appear to have, a financial, personal, or professional interest.
A. Procedures for IRB Members. The following procedures govern the management of Conflicts of Interest in the review of research by the IRB

i. If an IRB member believes that a conflicting interest might impact, or appear to impact, IRB deliberations or the protection of human subjects, the member must declare the presence of the conflict to the IRB and absent himself or herself from any deliberative IRB discussion or vote on the research. There are no exceptions from this requirement.

ii. In most cases, it is not necessary for the IRB member to disclose to the IRB the details of any COI for which the member voluntarily absents herself or himself from the IRB’s deliberative discussion and vote, and limits herself or himself to answering questions posed by the IRB. However, there may be circumstances in which it is in the best interests of the individual, HSS, and/or the human subjects involved for the IRB member to make a complete, written disclosure to the IRB. IRB members are expected to use their best judgment to ensure that all IRB deliberations take place without any appearance or possibility of a COI.

iii. IRB members must complete the IRB member Conflict of Interest Declaration before each IRB meeting. This form addresses both financial and non-financial COIs. IRB members who declare a possible COI will leave the meeting during the IRB’s deliberative discussion or vote on the relevant action.

iv. Any IRB member who has any interest (whether a Financial Interest or other personal or professional interest) in the research under consideration must recuse himself/herself from participation in or voting on the initial or continuing review of the research. The member may be present to answer questions posed by the IRB, but any other IRB activity – including the final discussion in which a determination is made as to how the IRB will vote on the protocol – must be conducted without the presence or participation of the conflicted IRB member.

v. All recusals/absences of IRB members because of a COI must be noted as such in the official IRB minutes. Recused members may not be counted toward the quorum for IRB action on the affected research.

vi. If the absence of the conflicted member results in a majority of the IRB members no longer being present at the meeting, no IRB action or
determination can take place until a majority of IRB members have again joined the meeting.

vii. If the (now absent) conflicted member was the only non-scientist member present at the meeting, no IRB action or determination can take place until an additional non-scientist member has joined the meeting.

B. Institutional Officials. To eliminate possible Conflicts of Interest involving HSS officials, HSS officials (including HSS’s Corporate Compliance Officer and HSS’s Human Subject Signatory Official) will not serve as voting members of HSS’s IRB.