I. PURPOSE

The purpose of this SOP is to describe the process for identifying and recording conflict of interest issues in IRB actions.

II. POLICY STATEMENT

The IRB recognizes that its members may be active researchers themselves or have other relationships that may create potential, perceived and actual conflicts of interest. The IRB has both a regulatory and ethical responsibility to be aware of, and respond appropriately to, potential, perceived and actual conflicts of interest. Accordingly, the IRB requires members with potential, perceived and actual conflicts of interest with respect to protocols being reviewed, to be identified in advance, and such members will not participate in the review of such protocols, except to provide information requested by the IRB. The definition of conflict of interest considers financial, as well as non-financial issues.

III. SCOPE

These policies and procedures apply to all IRB members and staff.

IV. DEFINITIONS

Immediate Family: Spouse or dependent children.

Chair: A chair for one or more of the convened IRBs.

Consultant (additional expertise): When the IRB determines that additional expertise is required for an IRB review, an individual with the appropriate expertise is asked to assist with a review of a proposal. Consultants are selected based on education, training, and experience with the research topic, the subject population to be recruited, the research test article, and/or the research intervention. Consultants may not provide expertise or advise when they have a conflict of interest.

Director, HSR: Director, Human Subjects Research.

Quorum: Quorum is a majority of the IRB members (more than half), including at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in non-scientific areas. When FDA-regulated research is reviewed, there shall be at least one member who is a physician. An IRB alternate may substitute for a member in order to meet quorum requirements at an IRB meeting.

V. PROCEDURES

A. Members Responsibilities

1. It is the responsibility of each IRB member to notify the IRB Chair or designee whenever the member believes that they have a conflicting interest with

respect to a study being reviewed. If a member is unsure of whether their interest creates a conflict of interest, the member is encouraged to discuss the matter in advance of the meeting or performing the review with the IRB Chair or designee.

2. For meetings of the convened board it is imperative that any such conflict of interest be identified, whenever possible, in advance of the meeting at which the submission is being reviewed, so that the member in question will not be assigned to review the submission. If invited by the Chair they may remain to answer questions, but will not be present for any of the deliberation or vote.

3. A member or consultant is automatically deemed to have a conflict of interest with respect to a protocol if:

(a) The member, consultant, or an immediate family member of the member or consultant is involved in the design, conduct, or reporting of the research.

(1) An IRB member who is listed on an IRB protocol (or Form FDA 1571) as a member of the study's Key Personnel but whose study activities are limited to (i) the performance of commercial services for the investigator (or performing other non-collaborative services meriting neither professional recognition nor publication privileges), while (ii) adhering to commonly recognized professional standards for maintaining privacy and confidentiality, is not considered to have a conflicting interest on this basis (e.g. investigational drug services pharmacist).

(b) The member, consultant, or an immediate family member of the member or consultant is a participant in the research.

(c) The member, consultant, or an immediate family member of the member or consultant has a Financial Interest in the research proposal.

(1) A Financial Interest can arise from anything of monetary value, including, but not limited to:

(a) Equity interests related to the research;

(b) Compensation related to the research (e.g. salary, consulting fees or honoraria); or

(c) Intellectual property related to the research (e.g. patents, copyrights and royalties).

(2) A Financial Interest is defined as:

(a) An equity interest in a publicly held company that exceeds $50,000 in value or 5% ownership interest as determined through reference to public prices or other reasonable measures of fair market value; or,

(b) Any interest in a privately held company; or

(c) Salary, consulting fees, royalties or other payments when the aggregated value of any remuneration to be received from the entity over the next twelve (12) months exceeds $25,000; or

(d) Any fiduciary role with the sponsor of the study (e.g. the IRB member serves as an executive to a company sponsoring the research or serves on the company's board of directors).

(3) The term Financial Interest does not include the following:

(a) Salary, royalties, or other remuneration paid by the Hospital or other primary institution to a person if the person is currently employed or otherwise appointed by the Hospital or primary institution, including intellectual property rights assigned to the Hospital or primary institution and agreements to share in royalties related to such rights;

(b) Any ownership interest in the Hospital or other primary institution held by the person, if the Hospital or other primary institution is a commercial or for-profit organization;

(c) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the person does not directly control the investment decisions made in these vehicles; and

(d) **Income from service on advisory committees or review panels for, or from seminars, lectures, or teaching engagements sponsored by an exempt entity**

(e.g., U.S federal, state, or local government agencies, universities, academic research institutes, other hospitals, non-profit foundations, non-profit professional societies, and most other U.S.-based non-profit entities).

4. In addition, a member may have a conflict of interest if the member has any interest that could actually be affected by the outcome of the study, or may appear to be affected by the outcome, or has any relationship that would prevent the member from being impartial, or that would appear to prevent the member from being impartial (e.g. the investigator must report to or is under the professional supervision of the IRB member). A conflict of interest is not automatically created when the member is in the same Division or Department as an investigator.

5. Any member with a conflict of interest will not be present when the submission is reviewed. If invited by the Chair, they may remain to answer questions, but will not be present for any of the deliberation or vote.

6. IRB members with a conflicting interest are not counted towards quorum for the submission for which they have a conflict.

7. The IRB minutes document when a member has a conflict of interest and is not present during the deliberation and vote.

8. The Director of HSR or IRB Chair will query potential consultants to determine whether or not they have any conflicts of interest. Those with a conflict cannot serve as a consultant for any submission for which they have a conflict.

B. IRB Chair and Staff Responsibilities

1. As part of the protocol review process, the staff will ensure that no submission is given for review to an IRB member if the member is a PI or a participant on a protocol. This procedure applies to studies to be reviewed by a convened IRB or by the expedited process.

2. At the time of reviewer assignment via the meeting agenda, each IRB member will be reminded to notify the IRB Chair or designee if there is a conflict of interest so that the submission may be re-assigned.

3. At the beginning of each meeting, the IRB Chair will remind the members of the Conflict of Interest policy. A COI statement for IRB members will be included with each IRB meeting agenda.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107(3)	21 CFR 56.107(3)

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 201: Composition and Management of the IRB	SOP 303: IRB Meeting Administration
Office of Compliance and Privacy SOP: Conflicts of Interest in Research	Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators (FDA, 2013)

VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.

IX. ATTACHMENTS

Statement on Conflict of Interest for Institutional Review Board (IRB) Members

X. REVISIONS:

07-20-2006	Initial approval date
04-17-2007	Revised to incorporate changes in IRB staff responsibilities.
06-10-2010	Revised to correct minor grammatical issues for consistency across SOPs.
03-11-2013	Minor administrative edits.
09-25-2018	Revised to clarify when members have conflicts of interest, including IDS pharmacists, include reference to the Statement on Conflict of Interest for Institutional Review Board (IRB) Members.
12-13-2022	Minor administrative edits.

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/13/22

Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS