I. PURPOSE

The purpose of this standard operating procedure is to outline the process for handling investigative team member conflict of interest issues.

II. POLICY STATEMENT

The HHS human subject protection regulations (45 CFR part 46) require that institutions performing HHS conducted or supported non-exempt research involving human subjects have the research reviewed and approved by an IRB whose goal is to help ensure that the rights and welfare of human subjects are protected. The comparable FDA regulations (21 CFR parts 50 and 56) require that FDA regulated research involving human subjects is reviewed and approved by such an IRB.

In conjunction with the above regulations, the IRB requires that all investigative team members listed on the study team complete and submit a financial disclosure form at the time of initial submission and whenever new personnel are added as members of the investigative team.

III. SCOPE

These policies and procedures apply to all investigators and team members.

IV. DEFINITIONS

Investigator: An individual at the institution who participates in the design, conduct, analysis, or reporting of research activities.

Investigative Team Member: All investigators, faculty, trainees, study coordinators, research assistants or other staff who interact with a human subject directly through an interaction, intervention, or identifiable health information (including data and biological specimens). The full definition is contained in CHOP Research Policy – Mandatory Education for Research Policy.

A. Principal Investigator

It is the responsibility of the principal investigator to ensure that all investigative team members complete and submit a financial disclosure form to the CHOP Conflict of Interest Committee via the electronic submission system. This requirement applies to studies requiring full board review, review using expedited procedures and to requests for determination of exemption from IRB review.

B. Investigative Team Members

It is the responsibility of all investigative team members to submit a study-specific financial disclosure form to the CHOP Conflict of Interest Committee. Team members may not participate in the research until the form has been submitted and reviewed. The reviewing IRB has final authority to decide whether the interest and management, if any,

allows the research to be approved.

C. IRB Staff Responsibilities

The Conflict of Interest Committee (COIC) is responsible for reviewing all disclosures and resolving all potential conflicts of interest.

1. When research that involves an institutional conflict of interest is reviewed, and the institutional conflict is known to the IRB at the time of IRB review, there shall be at least one member who is non-affiliated present during convened IRB meetings.

2. In the event that a potential conflict of interest has been identified or not yet adjudicated by the COIC at the time of IRB review, then the following procedures will be followed.

   (a) If the principal investigator or any other investigative team member has a potential conflict of interest or an investigative team member has not yet submitted a study-specific disclosure, the IRB may review but will not grant final approval for the research until the IRB is notified that all outstanding issues have been resolved.

   (b) If the institution has a potential conflict of interest, the IRB may review but will not grant final approval for the research until the IRB is notified that all outstanding issues have been resolved.

3. When the COIC determines that there is a conflict of interest that requires management, the IRB will ensure that the informed consent document includes required disclosures (if applicable) and that the research plan complies with any limitations on investigative staff (e.g., limitation on whom may obtain consent).

4. When the COIC determines that there is a conflict of interest that requires management and an external IRB is the Reviewing IRB, the investigative team will provide the management plan to the Reviewing IRB.

V. APPLICABLE REGULATIONS AND GUIDELINES

42 CFR 50.603, 50.604(b), 50.605(a),	21 CFR 54 (1)(4)
45 CFR 94.3, 94.4(b), 94.5(a)	

VI. REFERENCES TO OTHER APPLICABLE SOPS

SOP 904: Policy on Conflicts of Interest in IRB Actions	

VII. RESPONSIBILITIES

Title	Responsibility
Director, HSR and Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
Conflict of Interest Committee	Responsible for reviewing and resolving potential conflict of interest issues

VIII. ATTACHMENTS

CHOP Financial Conflict of Interest Policy

IX. REVISIONS:

06-09-2010 Revised to provide clarification, note updated financial disclosure form and removed references to paper application that have been replaced with the electronic IRB system.

07-07-2010 Revisions to reflect AAHRPP's recommendations including specifying that the IRB has the final authority to determine whether or not the research may be approved.

01-24-2017 Revisions to reflect electronic submission system for the Conflict of Interest Committee and the review of research involving institutional conflict of interest

12-13-2022 Revisions to reflect current processes

X. 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