1. Policy

All Institutional Review Board (IRB) members and IRB consultants shall disclose in writing to the IRB all conflicts of interest (COI) for themselves and their spouses/domestic partners, parents, siblings and their spouses, and dependent children. For purposes of this policy, a conflict of interest may be identified as either financial in nature (such as when an IRB member or consultant holds an economic interest in the research) or non-financial in nature (such as when an IRB member or consultant participates in the research or will be included as a co-author on a publication from the research), either of which could affect or appear to affect the design, conduct, oversight, or reporting of the research project. An IRB member or consultant shall be considered to have a financial COI with anything of monetary value when the member/consultant or the member’s spouse/domestic partner, parents, sibling and their spouses, and dependent children has any of the following, but not limited to:
   a. Ownership interest, stock options, or other economic interest related to the research, which involves the sponsor, product, or service being tested;
   b. Compensation related to the research;
   c. Proprietary interest related to the research including, but not limited to, patent, trademark, copyright, or licensing agreement;
   d. Interests in dividends or similar interests derived during the preceding calendar year;
   e. Any other reason that the member/consultant believes that they cannot provide an independent review.

Non-financial COIs that require disclosure include but are not limited to:
   a. Participation in the human research project as key study personnel;
   b. Co-Author on a publication of the human research project’s results;
   c. Other relationships which may influence judgment of the IRB member in reviewing the human research project:
      i. is a direct supervisor or trainee of the investigator(s)
      ii. is related to an investigator whose protocol is under consideration
      iii. has a prominent role in a directly competing research team or product
      iv. has a close personal relationship with an investigator or for other reasons feels unable to render a fair and unbiased review.

An IRB member or consultant with either a financial or non-financial conflict of interest in a research project involving human participants may not participate in the IRB review of that research. The IRB shall not approve a human research protocol where a conflict of interest is not managed or eliminated, and the IRB has the final authority to determine whether a conflict of interest has been managed or eliminated appropriately for research participant protection.

IRB members and consultants shall cooperate fully with the IRB and any other individuals or groups involved in the review of the pertinent facts and circumstances regarding any conflict of interest disclosed.

This policy is not intended to prohibit IRB members’ relationships with companies that have no influence on the design, conduct, or reporting of a human research project and that
occur prior to the initiation of a sponsored research project or after publication of its results. However, that notwithstanding, compensation in the form of an economic interest that may be affected by the outcome of the research project shall be avoided. (Examples of conflicts of interest due to compensation that require disclosure pursuant to this Policy include, but are not limited to, consulting agreements; speaking or other fees; honoraria; gifts; licensing revenues; equity interests; loans or notes, including stock options, regardless of value; expectations of receiving equity interests; and/or other fees or compensation received from sponsors.

2. Scope
This SOP applies to all University IRB members and consultants to the IRBs.

3. Responsibility

3.1 IRB Member/Consultant Responsibilities

3.1.1 The IRB member/consultant shall evaluate whether a conflict of interest exists, and he/she shall disclose any identified conflicts to the IRB at the next IRB meeting. IRB members and consultants shall disclose to the IRB all conflicts of the IRB member/consultant, their spouse/domestic partner, and their dependent children with regard to a research project involving human participants. Such disclosure shall be sufficiently detailed and timely to allow the IRB Administrator to transfer the project to another IRB or allow time for an alternate member or consultant to attend the IRB meeting.

3.1.2 If an IRB member/consultant discovers that he/she has a conflict of interest during the conduct of a research project over which the IRB provides oversight, the IRB member/consultant shall report the conflict to the IRB at the next IRB meeting.

3.1.3 IRB members/consultants shall cooperate with the IRB and other officials in their review of the conflicts of interest issues and shall comply with all University requirements to eliminate or manage the conflict before the IRB will approve the project or continue the project.

3.2 IRB Responsibilities

3.2.1 After the IRB member/consultant discloses to the IRB a potential conflict of interest, the IRB shall require the member/consultant to recuse him/herself from review of the research project.

3.2.2 Upon the member’s/consultant’s recusal, the IRB shall review the research project pursuant to HRPP policy (SOP 403: Initial Review – Criteria for IRB Approval, SOP 404: Continuing Review, SOP 405: Modifications, and SOP 407: Unanticipated Problems Involving Risks to Participation or Others and Protocol Deviations, SOP 903: Non-Compliance/Scholarly Misconduct.)

4. Applicable Regulations and Guidelines

21 CFR 56.107 (e)
45 CFR 46.107 (e)
42 CFR Part 50 Subpart F
5. References to Other Applicable SOPs and Policy
   303B: IRB Meeting Administration
   403: Initial Review – Criteria for IRB Approval
   404: Continuing Review
   405: Modification/Notification
   407: Protocol Deviations and Unanticipated Problems

Institutional Conflict of Interest Policies maintained by the respective Vice Presidents

6. Attachments
   None

7. Process Overview

   7.1 Disclosures
      7.1.1 IRB members will disclose to the IRB in writing, financial and non-financial
      conflicts of interests when they are appointed to the IRB. The IRB Chair will
      remind IRB members to report disclosures to the IRB on at least an annual
      basis and as needed to reflect changes that add or delete conflicts of
      interest.

      7.1.2 The HRPP Director and IRB Chair shall review disclosures to determine
      whether a conflict of interest exists and to determine appropriate
      management of the conflict of interest.

   7.2 Prior to a Convened IRB Meeting
      7.2.1 The IRB Administrator will include the definitions and examples of potential
      financial and non-financial conflicts of interest with each IRB meeting
      agenda. IRB members will be asked to disclose any potential conflicts of
      interest relating to any review item to the IRB Administrator, IRB Chair or
      IRB designee prior to each IRB meeting. Once the IRB office receives
      notice of a recusal, the IRB Administrator will seek an alternate IRB member
      to join the meeting for the review of that project, if necessary to meet
      quorum Primary and secondary reviewers will be reassigned as necessary
      to manage conflicts of interests.

      7.2.2 The IRB Administrator will check the IRB agenda prior to the meeting to
      identify IRB members who may have a conflict of interest due to their
      participation as key study personnel on agenda items. If a conflict of interest
      is identified, the research project is assigned to another member who does
      not have a conflict of interest.

      7.2.3 An IRB member who has a conflict of interest with regard to a research
      project that will be reviewed at a convened IRB meeting must notify the IRB
      office of the conflict prior to the meeting and will recuse him/herself from
      discussion and voting on that research project.

   7.3 At the Convened IRB Meeting
7.3.1 At the beginning of each convened IRB meeting, the IRB Chair or IRB designee will ask the members if anyone has a financial or non-financial conflict of interest with regard to any of the research projects that will be reviewed at the meeting. The HRPP Director or IRB Chair or IRB designee will announce that members with a conflict of interest must recuse themselves from deliberation and voting on that research protocol.

7.3.2 Any IRB member who has a conflict of interest with regard to a research project that will be reviewed at the convened IRB meeting will recuse him/herself from the convened IRB meeting for the discussion and voting on that research project. The recused member can answer questions from the IRB but cannot be present for IRB deliberations and voting. If the conflict affects quorum, see SOP 303B: IRB Meeting Administration.

7.3.3 The recusal of the IRB member for conflict of interest is recorded in the IRB meeting minutes.

7.4 Expedited Review

7.4.1 IRB members who are conducting expedited review must disclose to the IRB Chair or IRB designee or HRPP Director any conflicts of interest they have related to the research project under review, and they must not review those items.

7.4.2 The IRB Administrator identifies IRB members who are conducting expedited review and who have a conflict of interest with a research project. Items identified to have a conflict of interest by the IRB Administrator are presented to an IRB Chair or IRB designee who does not have a conflict with the research project.