Title: IRB MEMBER AND CONSULTANT CONFLICT OF INTEREST

1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to outline the IRB member and IRB consultant responsibilities regarding required disclosure of conflicts of interest when reviewing applications for human participants research.

2.0 Policy:
It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) that all conflicting interests of an IRB member and consultant be declared before review of any research under IRB jurisdiction. IRB members and consultants with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must recuse themselves from the meeting during the IRB’s deliberative discussion. No IRB member or consultant may participate in the review of or vote on any initial or continuing application, amendment, or other matter involving research in which he or she has a conflict of interest. A conflict of interest is assumed to be present when the member/consultant, or an immediate family member of the member/consultant is the Principal Investigator, faculty advisor, or member of the research team on any research being reviewed by the IRB or when the member/consultant has a financial interest in the sponsor of research under consideration, or when the outcome of the research could materially impact financially the member/consultant or a member of their immediate family.

IRB members and consultants with the following financial interests are considered to have a conflicting interest:

- Ownership interest (equity or stock options) of any value, unless it meets four tests:
  - Value when aggregated for the immediate family does not exceed $10,000 when referenced to publicly traded prices or other measure of fair market value.
  - Value when aggregated for the immediate family does not exceed 5% in any one entity.
  - Publicly traded on a stock exchange.
  - No arrangements have been made where the value of the interest will be affected by the outcome of the research.

- Compensation of any amount, unless it meets two tests:
  - Amount when aggregated for the immediate family did not exceed $10,000 in the past 12 months.
  - No arrangements have been made where the amount of compensation will be affected by the outcome of the research.

- Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.

- Board or executive relationship related to the research, regardless of compensation.

3.0 References and Reference Documents:
45 CFR 46

4.0 Procedure:

4.1 Individual With Conflict Responsibilities.

4.1.1 Each IRB Member must review this procedure, sign the Conflict of Interest Disclosure Agreement and return the signed agreement to ORIP. ORIP will distribute the disclosure agreement to members for review and signature on an annual basis.
4.1.2 Each consultant must read this procedure, sign a Conflict of Interest Disclose Agreement and disclose any conflicting interest before reviewing a research protocol.

4.1.3 At the initiation of the IRB meeting, the IRB Chair or designee will call upon IRB members in attendance at the meeting to declare any conflicting interests with items on the agenda.

4.1.4 IRB Members with a conflicting interest may not participate in any portion of the review of research activities and shall excuse themselves from discussions at IRB meetings of an application or other matter in which they have a conflict of interest. This is recorded in the IRB minutes along with the name of the IRB member. Members may provide information requested by the IRB prior to or after formal deliberations.

4.1.5 The IRB Chair or designee must excuse himself or herself from reviewing applications for exemption or expedited review and amendments or continuations when a conflict of interest is present. The Chair appoints another IRB member to review such applications or research activities.

4.1.6 All IRB Members and consultants are encouraged to avoid the appearance of a conflict of interest that would compromise their ability to make a fair, impartial, and ethical decision on any IRB matter and to excuse themselves from decision-making in such instances. IRB members may recuse themselves from the discussion and vote for any reason, if they feel it is necessary to avoid any appearance of a conflicting interest.

4.2 ORIP Responsibilities.

4.2.1 The ORIP Director or designee will review this SOP and the Policy on Conflict of Interest for Research Investigators with each member and consultant to determine whether the member or consultant has a conflicting interest. Consultants who have a conflicting interest with the review will not be used.
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