1.7 IRB Member, Consultant, Staff and Guest Conflict of Interest Identification and Management

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for the identification and management of IRB member, consultant, staff and guest potential conflicts of interest. For the purpose of this policy, staff refers to IRB Analysts (whether voting members or not) and other employees of the ORA.

2.0 Policy

It is the policy of the Organization that:

- 2.1. All financial and non-financial interests which may represent a conflict of interest for an IRB member, consultant, staff or guest must be self-identified to the best of the individual's knowledge, and appropriately managed to prevent such conflicts from interfering with the objectivity and validity of the review process.
- 2.2. Any financial interest of any monetary value by an IRB member, consultant, staff or guest at the meeting is considered a conflict of interest for the purposes of this policy.
- 2.3. Disclosure of the specifics of the conflict to the IRB and ORA is not required.

3.0 Definitions

- 3.1. Covered Persons are IRB members, consultants, staff, or guests at an IRB meeting, and the immediate family members of a Covered Person (spouse, dependent children, parents or anyone that a Covered Person may claim as a dependent under the Internal Revenue Code).
- 3.2. Conflicts of Interest are situations in which financial or non-financial interest may compromise, or have the appearance of compromising, a covered person's professional judgment or objectivity in reviewing or evaluating research involving human subjects.
  Note: In general, the covered person is not considered to have a conflict of interest if 1) the individual serves on the sponsor's scientific advisory board for an area unrelated to the research under review; or 2) the individual serves on an NIH study section or FDA advisory committee, where it has been determined by the NIH/FDA that a conflict does not exist.
  - 3.2.1. Financial Interest includes any of the following:
    - 3.2.1.1. Salary, royalties (or a commitment for future royalties), consulting fees, honoraria, gift(s), or other payments that has been received in the last twelve months, will be received while the research is being conducted or will be received within twelve months after the research is completed.
    - 3.2.1.2. An equity interest in the sponsor of the research (excluding mutual funds).
    - 3.2.1.3. A position as director, officer, partner, trustee, or any other significant position in the company sponsoring the research or such position in the past twelve months.
    - 3.2.1.4. Patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving the Organization.
    - 3.2.1.5. Financial interest (as defined above) in a company which has a marketed product, or is in the process of developing a new product which the covered person knows or would be reasonably expected to know, is, or will be, in direct market competition with the product in the protocol under IRB review.
  - 3.2.2. Non-financial interest is a personal or professional circumstance that includes (but is not limited to):
    - 3.2.2.1. Serving as an investigator, participating personnel, or coordinator for the protocol, or serving as a faculty advisor for a student as PI
    - 3.2.2.1. Having a personal relationship, or a conflict, with any research personnel listed on the IRB application which would compromise, or have the appearance of compromising, a covered person's professional judgment or objectivity in reviewing or evaluating research.
- 3.5. Guests are persons attending the IRB meeting who are neither members, non-voting alternates, or IRB staff. Guests may be organizational officials (for example, Chief Compliance officer, or Privacy Officer), legal counsel, representatives of other components of the HRPP (for example, the FPBCC Scientific Review Committee) or other persons specifically invited to attend.

4.0 Procedures for identification and management of conflict of interest by

members and consultants

- 4.1. IRB members (including IRB analysts serving as IRB members) must notify the ORA if they have a conflict related to any protocol being reviewed by the board at a which they are attending. If the member is assigned to review any action related to a protocol for which they have a conflict, they must notify the ORA in advance of the meeting so the protocol can be re-assigned to a non-conflicted member.
- 4.2. Consultants will be provided with this policy and must certify that they do not have a conflict of interest regarding the protocol on which they were asked to consult. They will be excluded from serving as a consultant if a conflict exists.
- 4.3. Prior to the beginning of each meeting, IRB members will be asked to declare the existence of any undisclosed conflicts, but are not required to describe the nature of the conflict.
- 4.4. An IRB member with a conflict of interest (other than serving as participating personnel; see below) must be absent from the meeting during discussion and voting for the protocol in question. The IRB member may not vote on any protocol where they have a conflict of interest. Upon request of the IRB, the member may provide information or respond to questions. The absent member is not counted towards determination of quorum during the vote on the protocol in question.
  - 4.4.1. An IRB member whose only conflict is that they are participating personnel on a protocol may serve as an assigned protocol reviewer, and may participate in the discussion regarding the protocol, may remain in the meeting during the vote, but will abstain from voting.
  - 4.4.2. If the conflicted member is attending the meeting by videoconference, “absent from the meeting” shall mean that the connection is terminated for the duration of the discussion and voting.
- 4.5. The IRB meeting minutes will specifically record when COI is the reason any IRB member is out of the room and did not vote.
- 4.6. An IRB member with a conflict of interest may not serve as an expedited reviewer for a protocol for which they have a conflict.

5.0 Procedures for identification and management of conflict of interest by IRB staff

- 5.1. IRB staff must notify the IRB Executive Chair/designee if a conflict exists with any proposed or active research study under the jurisdiction of the IRB.
- 5.2. IRB staff who have a conflict are excluded from serving as the primary IRB analyst assigned to process the study in question.
  - 5.2.1. IRB staff who have previously served as study personnel for an active protocol may serve as the primary IRB analyst assigned to process the study; however, they may not be the sole expedited reviewer for any non-compliance, AEs or UPs in which they were directly involved during their tenure as study personnel.
- 5.3. IRB staff with a conflict of interest must be absent from the meeting during discussion and voting for the protocol in question.

6.0. Procedures for identification and management of conflict of interest by guests at the IRB meeting

- 6.1. Guests with a conflict of interest must be absent from the meeting during discussion and voting for the protocol in question.

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Revised 10/10/2022 - Added identification and management of COI for a guest at IRB meeting; clarified that any financial interest by IRB members, consultants, staff and guests at the meeting is considered a significant financial interest within the context of this policy; clarified definitions of financial and non-financial COI; added definition of guest; clarified timing of disclosure of COI by IRB members; added IRB member whose only conflict is that he/she is participating personnel on a protocol may serve as protocol reviewer, and may participate in the discussion regarding the protocol, may remain in the meeting room during the vote, but will abstain from voting; added that IRB staff with COI must leave room during the discussion and voting phases of the review of the protocol in which they have a conflict; deleted option for member with COI to request exception from recusal; stylistic changes for clarity. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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