SOP Title	Managing Conflicts of Interest – Investigators
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		Oct 1, 2021
Dr. Philip Jones Chair, Health Sciences Research Ethics Board		Oct 1, 2021

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the potential conflicting interests for Investigators and also describes the requirement and procedures for disclosures and management of conflicts of interest.

2. GENERAL POLICY STATEMENT

Conflict of interest (real, potential or perceived) arises when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A conflict of interest may exist even if no unethical or improper acts result from the conflict.

Investigators and research staff should identify and manage conflicts of interest to maintain the public confidence and trust to maintain the independence and integrity of the ethics review. If a conflict of interest cannot be avoided, procedures should be put into place to mitigate the conflict.

The standard that should guide decisions about determining conflicts of interest is whether independent observers could reasonably question whether the individual's actions or decisions could be based on factors other than the rights, welfare, and the safety of the participants.

This SOP is not intended to prohibit Investigator relationship with companies, however, the HSREB should ensure that participants protection, the integrity of the ethics review, and the conduct of a research study are not jeopardized by an unidentified and unmanaged conflict of interest.

A special case arises when a Principal Investigator on a research project is a family member of a Co-Investigator. Although this situation does not in any way mean a conflict of interest is necessarily present, it is a nuanced situation where conflicts are possible. For example, if the Principal Investigator has a financial conflict in a project, ensuring that a family member Co-Investigator does not perform statistical analysis on the project becomes quite important. Another example is if a Principal Investigator is both a parent and a supervisor to a Co-Investigator. In this situation, additional steps may be required to ensure the family member being supervised has another study team member to go to in case of disagreement. Asking about these relationships is a responsibility of the HSREB and it does not imply that anything wrong has occurred.

3. RESPONSIBILITY

This SOP applies to all Investigators who submit research for HSREB review, and to all HSREB members including the HSREB Chair and Vice Chair(s).

Investigators are responsible for disclosing any potential conflicts of interest to the HSREB.

The HSREB is responsible for determining whether the disclosed conflict of interest is likely to affect or appear to affect the design, conduct, or reporting of the study.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Investigator Disclosure of Conflicts of Interest

5.1.1. Investigators submitting research applications to the HSREB are required to declare any conflicts of interest including those of his/her sub-Investigator(s), research staff, and their immediate families (which includes spouse, domestic partners and dependent child), and close relationships;

5.1.2. Such disclosure shall be in writing and sufficiently detailed to allow accurate and objective evaluation of the conflict;

5.1.3. The Investigator shall disclose any conflicts to the HSREB at the following times:

- With the initial HSREB submission application,
- At each continuing review of the project,
- Whenever a conflict of interest arises, such as changes in responsibilities or financial circumstances;

5.1.4. The Investigator shall cooperate with the HSREB and with any other officials involved in the review of the pertinent facts and circumstances regarding any conflict of interest disclosed, and shall comply with all the requirements of the HSREB and with his/her institutional conflict of interest policies to eliminate and/or manage the conflict;

5.1.5. The Investigator shall ensure that all requirements from any conflict of interest reviews are appropriately incorporated into the corresponding informed consent documents and protocol, as applicable.

5.2. HSREB Review of Investigator Conflict of Interest

5.2.1. The HSREB will review each application for disclosure of conflicts of interest;

5.2.2. If the Investigator indicates on the HSREB application that a conflict exists, the HSREB will determine whether the disclosed conflict of interest is likely to affect or appear to affect the design, conduct, or reporting of the study;

5.2.3. The HSREB review should focus on those aspects of the conflicts of interest that may reasonably affect human participant protection and the steps taken should be context-based and commensurate with the risks;

5.2.4. In determining the appropriate action, the HSREB may take into consideration information presented by the Investigator such as:

- The nature of the research,
- The magnitude of the interest or the degree to which the conflict is related to the research,
- The extent to which the interest could affect the research,
- The fact that a specific individual is unique in his/her clinical or scientific qualifications to conduct the research,
- The degree of risk to the human participants involved in the research that is inherent in the research protocol, and/or
- The management plan for the conflict of Interest already developed by the Investigator.

5.2.5. The HSREB may approve the research and may require a management plan, which may include changes at the Investigator or sponsor's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to the following:
- Divestiture or termination of relevant economic interests,
- Mandating Investigator recusal from a study,
- Modifying or limiting the participation of the Investigator in all or in a portion of the research,
- In cases involving equity, by imposing a ban on insider trading or requesting that the transfer of securities to an independent financial manager or blind trust, or limiting the timing of sales or distributions,
- Monitoring research, i.e. independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data),
- Independent clinical review of appropriateness of clinical care given to research participants, if applicable,
- Monitoring the consent process and/or
- Disclosure of the conflict to institutional committees, research participants, journals, and the data safety monitoring boards;

5.2.6. The HSREB has the final authority to determine whether a conflict of interest has been eliminated or managed appropriately;

5.2.7. Any conflict of interest management plan will be documented in the project file. Any discussion at the full HSREB meeting regarding the conflict of interest and the management plan will be documented in the HSREB meeting minutes;

5.2.8. After a review by the HSREB and input by the appropriate institutional representative, if applicable, the HSREB may reject research that involves a conflict of interest that cannot be appropriately managed.

5.3. **Documentation**

5.3.1. All conflicts of interest should be documented within the submission form submitted in the WREM system.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);

6.2. U.S. Office for Human Research Protections (OHRP) "*Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*";

6.3. U.S. Food and Drug Administration (FDA) Guidance Document "*Financial Disclosure by Clinical Investigators*";

6.4. FDA Information Sheets, *Guidance for Institutional Review Boards and Clinical Investigators*, Section II.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
105B.001	Original	01/21/2014
105B.002	Reformatting and minor administrative revisions for clarity	05/22/2014
105B.003	Minor administrative revisions for clarity	05/10/2016
105B.004	Minor administrative revision	08/10/2018
105B.005	Minor Administrative Changes	09/06/2018
105B.006	Update Section 2 ("General…" to include information regarding special case of the Principal Investigator and a co-investigator being related.	09/20/2021