Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Conflicts of Interest - Investigators
REB SOP # 023B

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Purpose:
This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) for Investigators and research staff engaged in human participant research, and the requirements and procedures for disclosure and managing COI.

Scope:
This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

Description:
COI (real, potential or perceived) arise 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 COI may exist even if no unethical or improper act results from the conflict.
Investigators and research staff should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or to mitigate the conflict.
This SOP is not intended to prohibit Investigator relationships with companies; however, the REB should ensure that participant protection, the integrity of the ethics review, and the conduct of the research are not jeopardized by an unidentified and unmanaged COI.
REBs should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.
The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the Investigators whose research is being reviewed, or by other professional and/or nonprofessional sources.
The standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual's actions or decisions are based on factors other than the rights, welfare and safety of the participants.

Procedure:

1) Investigator Disclosure of Conflicts of Interest:

- Investigators submitting research applications to the REB are required to declare any COI including those of his/her co-Investigator(s), research staff, and their immediate families (which includes spouse, domestic partners and dependent child), and close relationships

- The Investigator is additionally required to provide information on the clinical trial budget, as applicable, when submitting a research application

- Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation

of conflict

- The Investigator shall disclose any conflicts to the REB at the following times:

- With the initial REB application
- At each continuing review of the project
- Whenever a COI arises, such as changes in responsibilities or financial circumstances

- The Investigator shall cooperate with the REB and with other officials involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the REB and with his/her organizational COI policies to eliminate and/or to manage the conflict

- The Investigator shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

- REB Review of Investigator Conflict of Interest

- The REB will review each application for disclosure of COI

- If the Investigator indicates on the REB application that a conflict exists, the REB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research

- The REB review shall focus on those aspects of the COI that may reasonably affect human participant protection and the steps taken should be context-based and commensurate with the risks

- In determining the appropriate action, the REB 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
- Whether 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
- The management plan for the COI already developed by the Investigator

- The REB may approve the research and may require a management plan, which may include changes at the Investigator's or sponsor's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:

- Divestiture or termination of relevant economic interests
- Mandating Investigator recusal from research
- Modifying or limiting the participation of the Investigator in all or in a portion of the research
- In cases involving equity, by imposing a bar on insider trading or requiring the transfer of securities to an independent financial manager or blind trust, or limited 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 organizational committees, research participants, journals, and the data safety monitoring boards

- The REB has the final authority to determine whether a COI has been eliminated or managed appropriately

- Any COI management plan will be documented in the final project files. Any discussions at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes

- After review by the REB and input by the appropriate Organizational Official, if applicable, the REB may reject research that involves a COI that cannot be appropriately managed.

Responsibility:
All REB members, REB Office Personnel and Investigators are responsible for ensuring that the requirements of this SOP are met.

Investigators are responsible for disclosing any real, potential or perceived COI to the REB. The REB is responsible for determining whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research.

References:

1) N2 CAREB REB SOPs v1 *SOP 105B.001* (September 2014) https://oicronca.box.com/s/95k7ydj574579ajvbe06

2) Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, December 2010: (short name: TCPS 2) http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

3) ICH: E6 - Guidance for industry: Good Clinical Practices (GCP): (April 1996) http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

4) U.S. Department of Health and Human Services (HHS): Code of Federal Regulations (CFR), Title 45 Part 46.103, Part 46.108 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) U.S. Department of Health and Human Services (HHS): Office for Human Research Protections (OHRP) Policy & Guidance Library http://www.hhs.gov/ohrp/policy/index.html

6) Ontario Shores Research Ethics Board Terms of Reference, Functions and Responsibilities (2009)