



IWK Research Ethics Standard Operating Procedures

Document # RE 2.203	Title: Disclosure and Documentation of Conflicts of Interest	Effective Date: February 1, 2023
Pages: 5	Responsibility of: Research Ethics Board	Date Approved: February 1, 2023

POLICY STATEMENT

Any Member who has a conflict of interest in any matter before the Board shall declare such interest to the Chair of the Board which will then determine what action, if any, should be taken to ensure integrity of the research and proper protection of the participants interests and welfare.

The TCPS2 defines conflict of interest as ‘The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another.’

This policy applies equally to actual, perceived or potential conflicts of interest, financial or otherwise.

DEFINITIONS

See Glossary of Terms

Recusal. Conflicted REB members leave the REB meeting before the vote on the item with which they have a conflict. When this occurs, the member does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.

Conflict of interest. A conflict of interest involves any situation in which an REB member, REO staff or REB consultant has any significant personal or financial interest in the proposed research or clinical investigation.

Types of conflict of interest include:

- Significant involvement in the preparation of the materials submitted to the REB for review or determination
- Participation in the research team: The REB member is listed as an investigator on the REB application, or is otherwise a member of the research team
- Supervision of the investigator: This refers to any situation in which the investigator is currently under the professional supervision of the REB member
- Supervision of the REB member by a member of the research team: This means that the investigator on the REB application has a supervisory or other official authority role with regard to the REB member
- Financial interest in the research
- Other potentially conflicting relationships with research sponsors: Examples include serving on a sponsor's board of directors, advisory board, scientific board, or safety board
- Personal relationship with the investigator: This is defined as having an immediate family relationship or other close personal relationship with the investigator, or with co-investigators who have a significant role in the research
- Competitive relationship with the investigator: This means the REB member is in direct competition with the investigator for limited resources (e.g., funding, sponsorship, space, equipment, research subjects), or the REB member is considered a personal or professional adversary of the investigator for reasons not related to the REB or REO. Whether this situation creates a conflict of interest for the REB member should be determined by the REB Chair or REO Manager

RESPONSIBILITY

Responsibilities are defined in this document for REO staff, REO management, REB members, REB chairs, and REB consultants.

PROCEDURES

Identification

A conflict may be discovered or identified at any stage of REB activity in any matter referred to it.

Disclosure

Voluntary disclosure. It is the responsibility of the REB member to disclose all known or potential conflicts of interest prior to engaging in any REB review or REO determination

activities.

Query at REB meetings

At the beginning of each meeting, the REB Chair will ask all members to disclose any conflict of interest concerning any of the items on the agenda.

REB consultants

In most cases, a possible consultant who discloses a conflict of interest does not provide consultation to the REB. However, a conflicted consultant may still be asked to provide consultation when the REB lacks specific expertise that is important to the review and an alternate consultant cannot be located. REB staff document the nature of the conflict in a Note to File, which is shared with the REB members and placed in the REB file. When the REB is provided with the consultant's information, it is accompanied by a statement that the consultant has a conflict.

Determination when not clear

When it is not clear whether a conflict of interest exists, the individuals listed below make a determination. The determination is based on gathering as much information as necessary from relevant sources.

Management of conflict of interest

- REO staff will not participate in review activities, pre-review, or regulatory determinations. The REO manager will assign these activities to another REO staff person with similar qualifications
- REB members (as reviewers). Will not serve as primary or expedited reviewers. If the conflict is disclosed after review assignment, the review is re-assigned to another REB member
- REB members (at the Table). Any conflict should be disclosed at the beginning of the REB meeting and certainly prior to the review of the relevant item. The Member should not participate in the discussion except to provide information at the REB's request, and will be recused before the vote. This recusal will be recorded in the minutes
 - Consultants. In most cases, a possible consultant who discloses a conflict of interest will not be asked to provide consultation to the REB. However, a conflicted consultant may still be asked to provide consultation when the REB lacks specific expertise that is important to the review and an alternative consultant cannot be located. REO staff will record the nature of the conflict in a Note to File, which will be shared with the REB members and placed in the REO file. When the REB is provided with the consultant's information, it will be accompanied by disclosure of the conflict. If the consultant's information has a negative effect on the REB's assessment of the research, the investigator will be provided an opportunity to respond

REFERENCES

1. 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, 2018: (short name: TCPS 2; Article 7.3)

2. ICH GCP Section 3.4

3. WHO Standards and operational guidance for ethics review of health-related research with human participants 2011 Section 4.9

4. CFR 46.107(e) and 21 CFR 56.107(e)

Forms/Records:

Form #	Form/Record Name
SOP 203	Disclosure and Documentation of Conflicts of Interest

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 8, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo