

SOP Title	Conflicts of Interest - Organization
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) in the relationship between the organization establishing the Non-Medical Research Ethics Board (NMREB) and the NMREB itself, and the requirements and procedures for disclosure and for managing potential COI within this relationship.

2. GENERAL POLICY STATEMENT

The SOP pertains to NMREB that reviews human participant research in compliance with applicable regulations and guidelines.

3. RESPONSIBILITY

All NMREB members and Office of Human Research Ethics (OHRE) Personnel are responsible for ensuring that the requirements of this SOP are met.

4. DEFINITIONS

See Glossary of Terms.

5. SPECIFIC POLICIES AND PROCEDURES.

Organizational policies should address the roles, responsibilities and process for identifying, eliminating, minimizing or otherwise managing COI relevant to research, including disclosure to NMREBs. Management of COI includes, but is not limited to, prevention, evaluation, disclosure and the application of appropriate remedies as defined by the organization.

The NMREB must be fair and impartial, immune from pressure by the sponsor, the parent organization and the Researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the NMREB must act independently from its parent organization, and avoid or manage real or apparent COI. The organization must respect the autonomy of the NMREB and ensure that the NMREB has the appropriate financial and administrative independence to fulfill its primary duties.

The standard that should guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether the NMREB actions or

decisions could be based on factors other than the rights, welfare, and safety of the research participants.

5.1. Disclosure of Conflict of Interest

- 5.1.1. All organizational employees must be familiar with the Conflict of Interest policy and must complete a Disclosure of Conflict of Interest Form(s) (if applicable) at the time of hire and annually thereafter, or as per organizational policy;
- 5.1.2. Prior to engaging in any of the professional activities listed in the Conflict of Interest Policy, employees must seek the approval of the appropriate Organizational Official to ensure that no conflict exists in doing so;
- 5.1.3. NMREB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the NMREB and the organization. The actions of the NMREB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;
- 5.1.4. NMREB meetings are closed to employees of the organization unless they are NMREB members, NMREB Office Personnel, permitted as observers, or invited by the NMREB to provide information, and only after signed confidentiality agreements are in place;
- 5.1.5. Organizational senior administrators shall not serve as NMREB members nor observe NMREB meetings when their presence may influence NMREB deliberations.

5.2. Management of Conflicts of Interest

- 5.2.1. The NMREB Chair or designee must be notified if an organizational COI relating to the NMREB is declared or discovered;
- 5.2.2. The NMREB Chair or designee must be notified immediately if any organizational employee attempts to, or appears to attempt to, influence the research ethics review process or to obtain preferential treatment;
- 5.2.3. The NMREB Chair or designee will review the available information to determine if a conflict exists, and to determine those aspects of the COI that might reasonably affect human participant protection;
- 5.2.4. The NMREB Chair or designee may require a management plan, which may include actions to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:
 - Divestiture or termination of relevant economic interest,

- Recusal of OHRE staff whose job status or compensation is impacted by research that is reviewed by the NMREB,
 - If organizational staff members are involved, inform the appropriate responsible organizational management personnel to develop and implement a management plan for remediation;
- 5.2.5. If the NMREB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the NMREB, the NMREB Chair or designee will bring this to the appropriate Organizational Officials for determination of the appropriate course of action;
- 5.2.6. In the event that the NMREB Chair or designee cannot bring the matter to the appropriate Organizational Officials because of an emergent situation or competing COI with the organization, the NMREB Chair or designee may escalate the issue to the Board of Governors.

6. REFERENCES

- 6.1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, (TCPS 2) <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
- 6.2. 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>
- 6.3. 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>

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N104C.001	Original	12/07/2015
N104C.002	Change ORE to OHRE	06/09/2016
N104C.003	Update to NMREB Chair & Administrative Corrections	05/11/2018
N104C.004	Updated NMREB Chair & Administrative Corrections; added references as they were accidentally missing in previous versions	03/03/2025