

Title	Conflicts of Interest - Organization
SOP Code	105C.001
Effective Date	2022-NOV-04

Site Approvals

Name and Title	Signature	Date (yyyy.mm.dd)
Dr. Lynne Lafave CHAIR, HREB	<i>L Lafave</i>	2022.11.04
Dr. Priscilla Wamucii RESEARCH COMPLIANCE OFFICER	<i>Priscilla Wamucii</i>	2022.11.04

1.0 PURPOSE

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

2.0 SCOPE

This SOP pertains to the Human Research Ethics Board (HREB), Mount Royal University

3.0 RESPONSIBILITIES

All HREB members, HREB Office Personnel and Organizational Officials are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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

The HREB must be fair and impartial, immune from pressure by sponsors and funders, the Organization and Researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the HREB must act independently from the Organization under whose authority they were established and given their mandate, and avoid or manage real, potential or perceived COI. The Organization must respect the autonomy of the HREB and ensure that the HREB 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 Organization's actions or decisions could be influenced by factors other than the rights, welfare and safety of research participants.

5.1 Disclosure of Conflict of Interest

- 5.1.1 All Organizational employees must be familiar with MRU Code of Conduct - Employees and the Conflict of Interest in Research 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 MRU Code of Conduct -Employees and the Conflict of Interest in Research Policy, employees must seek the approval of the appropriate Organizational Official to ensure that no conflict exists in doing so;
- 5.1.3 HREB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the HREB and the Organization. The actions of the HREB 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 HREB meetings are closed to employees of the organization unless they are HREB members, HREB Office Personnel, permitted as observers, or invited by the HREB to provide information, and only after signed confidentiality agreements are in place;

5.1.5 Organizational senior administrators shall not serve as HREB members nor observe HREB meetings when their presence may influence HREB deliberations.

5.2 Management of Conflicts of Interest

5.2.1 The HREB Chair or designee must be notified if an organizational COI relating to the HREB is declared or discovered;

5.2.2 The HREB Chair or designee must be notified immediately if any organizational employee attempts to, or appears to attempt to, influence the ethics review process or to obtain preferential treatment;

5.2.3 The HREB 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 research participant protection;

5.2.4 The HREB 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 interest,
- Recusal of HREB Office Personnel whose job status or compensation is impacted by research that is reviewed by the HREB,
- 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 HREB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the HREB, the HREB Chair or designee will bring this to the appropriate Organizational Officials for determination of the appropriate course of action;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 105C.001	2022.11.04	Original version