

| | |
|-----------------------------------|---|
| TITLE | 105A: Conflicts of Interest – HREB Members and HREB Office Personnel |
| SCOPE | The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University |
| RESPONSIBILITIES | The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator |
| APPROVAL AUTHORITY | The Vice-Provost, Research & Graduate Studies |
| EFFECTIVE DATE | November 14, 2019 |
| Supersedes documents dated | N/A |

1.0 PURPOSE

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) for Human Research Ethics Board (HREB) members (including the HREB Chair and any ad hoc advisors) and HREB Office Personnel, and describes the requirements and procedures for disclosure and management of COI.

2.0 DEFINITIONS

See Glossary of Terms.

3.0 PROCEDURE

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.

HREBs 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 HREB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or non-professional 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.

3.1 HREB Reviewer Assignment

- 3.1.1 The HREB Chair or designee reviews the agenda prior to the HREB meeting to identify potential COI;
- 3.1.2 When the agenda is distributed, HREB members are expected to disclose as soon as possible, any conflicting interest(s) for any of the projects on the agenda;
- 3.1.3 If a member is unclear as to whether a COI exists, he or she must contact the HREB Chair or designee to seek clarification. The HREB Chair or designee will determine whether the circumstances should be defined as a COI and the member shall follow the HREB's decision regarding any actions required to mitigate his/her real or perceived COI;
- 3.1.4 If a COI is identified in the reviewer assignments, the project is assigned to another HREB member.

3.2 Full Board Meeting

- 3.2.1 At the outset of the meeting, HREB members are reminded of their obligation to orally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the HREB meeting minutes;
- 3.2.2 If a COI is declared and determined as such, the HREB member may be asked to provide information about the research, but must be recused for the deliberation and decision;
- 3.2.3 The HREB member's recusal will be recorded in the minutes and the HREB member will not be counted towards quorum.
- 3.2.4 If recused, the HREB member should abstain from voting on/approving the minutes of that meeting.

3.3 Delegated Review

- 3.3.1 The HREB Chair or designee will assess projects undergoing the delegated review process to determine potential COI;
- 3.3.2 HREB members involved in the delegated review process are expected to disclose any conflicting interests;
- 3.3.3 If a COI is identified, the project is assigned to another HREB member.

3.4 HREB Chair

- 3.4.1 In the event that the HREB Chair declares a COI, the Vice-Chair or alternate HREB member will assume the HREB Chair's responsibilities for the specific project(s).

3.5 HREB Office Personnel

- 3.5.1 All HREB Office Personnel are expected to disclose any conflicts that arise and any HREB Office Personnel whose job status or compensation is

impacted by research that is reviewed by the HREB must recuse themselves when such research is reviewed;

- 3.5.2 Any disclosure of a COI by HREB Office Personnel should be referred to the HREB Chair or designee for the development of a management plan;
- 3.5.3 If HREB Office Personnel are unclear as to whether a COI exists, they must contact the HREB Chair or designee to seek clarification. The HREB Chair or designee will determine whether the circumstances should be defined as a COI.

3.6 External Ad Hoc Advisors

- 3.6.1 At his/her discretion, the HREB Chair or designee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the HREB;
- 3.6.2 All ad hoc advisors must sign a *Confidentiality of Information and Conflict of Interest Agreement* prior to commencement of their consultation, and disclose any COI to the HREB Chair.
- 3.6.3 Any disclosure of a COI by an ad hoc advisor should be referred to the HREB Chair or designee for the development of a management plan, as applicable.
- 3.6.4 If ad hoc advisors are unclear as to whether a COI exists, they must contact the HREB Chair or designee to seek clarification. The HREB Chair or designee will determine whether the circumstances should be defined as a COI.

3.7 Documentation

- 3.7.1 All HREB members, guests and ad hoc advisors sign a *Confidentiality of Information and Conflict of Interest Agreement* and agree to abide by the HREB COI and confidentiality policies;
- 3.7.2 HREB members sign a *Confidentiality of Information and Conflict of Interest Agreement* annually, or as determined by the organization;
- 3.7.3 The signed *Confidentiality of Information and Conflict of Interest Agreement* is filed in the HREB office;
- 3.7.4 The HREB minutes will record any COI that are declared on any of the projects under review at the HREB meeting, and the decision on the management of the conflict;
- 3.7.5 The HREB minutes will also record the recusal of an HREB member;
- 3.7.6 At the time of hire, all HREB Office Personnel sign a *Confidentiality of Information and Conflict of Interest Agreement* as a condition of their employment with the organization agreeing to abide by the COI and confidentiality policies of the organization. HREB Office Personnel must also comply with HREB COI SOPs;

- 3.7.7 The signed *Confidentiality of Information and Conflict of Interest Agreement* will be retained;
- 3.7.8 The HREB management plan for Research COI declarations will be documented in the appropriate research files. Any discussion at the HREB meeting regarding the COI and the management plan will be documented in the HREB meeting minutes.

4.0 REFERENCES

See References.

5.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP 105A | November 14, 2019 | Original version |
| | | |
| | | |
| | | |
| | | |