

<b>TITLE:</b>	Standard Operating Procedure (SOP) Disclosure of Conflict of Interest – Organization	<b>NUMBER:</b>	NSHA REB-SOP-1-006C
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	NSHA REB Members and REB Office Personnel		

## 1. 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 REB itself, and the requirements and procedures for disclosure and for managing potential COI within this relationship.

## 2. POLICY:

The Nova Scotia Health Authority's Conflict of Interest policy (AD-BOD-001) addresses the roles, responsibilities and process for identifying, eliminating, minimizing or otherwise managing COI relevant to research, including disclosure to the REB. Management of COI includes, but is not limited to, prevention, evaluation, disclosure and the application of appropriate remedies as defined by the organization.

The REB 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 REB must act independently from the Nova Scotia Health Authority (NSHA), and avoid or manage real or apparent COI. NSHA must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties.

The standard that will guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether the REB actions or decisions could be based on factors other than the rights, welfare, and safety of the research participants.

All REB members and REB Office Personnel are responsible for disclosing any real, potential or perceived COI and for ensuring that the requirements of this SOP are met.

## 3. DEFINITIONS:

**Conflict of interest:** circumstance of a person (e.g., Investigator or Research Ethics Board (REB) member) or organization in a real, perceived or potential conflict between

their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.

## **4. PROCEDURES:**

### **4.1. Disclosure of Conflict of Interest**

- 4.1.1. All NSHA 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;
- 4.1.2. Prior to engaging in any of the professional activities listed in the Conflict of Interest Policy, employees must seek the approval of NSHA Legal Services to ensure that no conflict exists in doing so;
- 4.1.3. REB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the REB and the Nova Scotia Health Authority. The actions of the REB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;
- 4.1.4. REB meetings are closed to employees of NSHA unless they are REB members, REB Office Personnel, permitted observers, or invited by the REB to provide information, and only after signed confidentiality agreements are in place;
- 4.1.5. NSHA senior administrators shall not serve as REB members nor observe REB meetings when their presence may influence REB deliberations.

### **4.2. Management of Conflict of Interest**

- 4.2.1. The REB Chair or designee must be notified if an organizational COI relating to the REB is declared or discovered;
- 4.2.2. The REB 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;
- 4.2.3. The REB 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;
- 4.2.4. The REB 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 REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB,
  - If organizational staff members are involved, inform the appropriate responsible organizational management personnel to develop and implement a management plan for remediation;
- 4.2.5. If the REB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the REB, the REB Chair or designee will bring this to NSHA Legal Services or the appropriate Organizational Officials for determination of the appropriate course of action;
- 4.2.6. In the event that the REB Chair or designee cannot bring the matter to NSHA Legal Services or the appropriate Organizational Officials because of an emergent situation or competing COI with the organization, the REB Chair or designee may escalate the issue to the Board authority.

## 5 REFERENCES

- 1) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Chapter 7

## 6 RELATED DOCUMENTS:

- 1) Confidentiality of Information and Conflict of Interest Agreement
- 2) Administrative Manual, *Conflict of Interest Policy*, AD-BOD-001
- 3) *Financial Conflict of Interest for National Institutes of Health (NIH), Public Health Service (PHS) and Health and Human Services (HHS) Funding*, RS 01-018

**Version History**

<b>Effective Date</b>	<b>Major Revisions (e.g. Standard 4 year review)</b>	<b>Minor Revisions (e.g. spelling correction, wording changes, etc.)</b>
September 29, 2017	Original Version	