Western S Research

SOP Title	Health Sciences Research Ethics Board (HSREB) Executive Working Group
Number Version	204.001
Effective Date	2021/06/15

Approvals

Name and Title of Signatories	Signature	Date yyyy/mm/dd
Erika Basile		
Director, Research Ethics and	5-22-0	June 14, 2021
Compliance	Clesso	00110 T 1, 2021
Dr. Philip Jones		
Chair, Health Sciences Research Ethics	TIM De hom	15 June 2021
Board		
	· 7	

1. PURPOSE

This standard operating procedure (SOP) describes the structure and function of the Health Sciences Research Ethics Board Executive Working Group.

2. GENERAL POLICY STATEMENT

Each member of the Health Sciences Research Ethics Board (HSREB) Executive Working Group (hereto referred to as the 'Executive') serves the HSREB membership, researchers, and Western Research by providing leadership in the development of practices and procedures to support the ethical review of human research. In order to fulfill their duties, Executive members must be versed in regulations governing human participants' protection and biomedical research ethics, and policies relevant to human research participant protection.

3. RESPONSIBILITY AND AUTHORITY

- 3.1 The Executive will be responsible to:
 - 3.1.1.Be apprised of external regulator requirements, and develop plans to ensure their translation and transmission to institutional policies, procedures and stakeholders;
 - 3.1.2.Lead in the development and/or review of institutional policies and procedures, including Standard Operating Procedures;
 - 3.1.3.Create and review draft REB guidance documents, policies and reports brought to its attention; provide direction regarding recommendations;
 - 3.1.4. Review reports associated with and impacting the human participant research, e.g. postapproval monitoring, training programs and other strategic initiatives; develop recommendations and action plans, as applicable;
 - 3.1.5.Provide leadership in preparation for and in response to regulatory assessments and associated reports; and
 - 3.1.6. Notify and engage the full HSREB of its decisions and actions, as appropriate.

4. **DEFINITIONS**

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Meetings

- 5.1.1. A face-to-face meeting is the principal forum used for Executive discussion and decisionmaking. At the HSREB Chair discretion, they may conduct an Executive meeting with all members attending via simultaneous videoconference or teleconference, provided everyone has received the review materials and quorum is met;
- 5.1.2. Meeting minutes will be taken and forwarded to the Chair;
- 5.1.3. Only those Executive members present (i.e., in person or via videoconference or teleconference) at the convened meeting may participate in the deliberation and final decision regarding approval;
- 5.1.4. Guests may be invited or permitted to attend Executive meetings, subject to the agreement of the REB Chair and execution of a Confidentiality and Conflict of Interest Agreement;
- 5.1.5. Meeting Frequency
 - 5.1.5.1. The Executive will meet at minimum twice a year;
- 5.1.6. Meetings will consist of Agenda topics that arise from the Executive's accountabilities;
- 5.1.6.1. Member recommendations to discussions may be communicated to the Chair and/or Executive through electronic means.

5.2. Decision Making

- 5.2.1. Typically, decisions will be made by consensus, where consensus is defined as widespread rather than unanimous agreement. Opportunity will be given for individual members to register their opposition;
- 5.2.2. From time-to-time where consensus cannot be reached, the HSREB Chair will forward the issue to the full HSREB.

5.3. Membership

- 5.3.1. With the exception of Office of Human Research Ethics staff, an Executive of the HSREB will be appointed by the HSREB Chair and in consultation with the Director, Research Ethics and Compliance.
- 5.3.2. The HSREB Executive will consist of the:
 - 5.3.2.1. HSREB Chair and Vice Chairs
 - 5.3.2.2. Director, Research Ethics and Compliance
 - 5.3.2.3. Office of Human Research Ethics staff

5.4. Conflict of Interest

- 5.4.1. All Executive members shall disclose any conflicts of interest (actual, apparent, perceived or potential) prior to the review and/or discussion of items on the meeting agenda.
- 5.4.2. All Executive members shall follow recusal requirements.

6. **REFERENCES**

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date yyyy/mm/dd
204.001	original	2021/06/15