External Review of the Newfoundland & Labrador Health Research Ethics Authority's (HREA) Health Research Ethics Board (HREB)

A review was conducted in response to a request by the Newfoundland and Labrador (NL) Health Research Ethics Authority (HREA) for an external review of the Health Research Ethics Board (HREB). The review was conducted from June to October 2018 and was led by Clinical Trials Ontario (CTO). It included an on-site review, interviews, and the review of HREB documentation and external comparative information.

The review focused on HREB review timelines, process and decision outcomes, REB workload and resources, and governance and accountability.

Based on the recommendations HREA Board has developed the following action plan:

Review Processes

Recommendations	Action	Status
Revise the Research Ethics Office screening procedures to reduce the number of screenings and individuals involved; ensure screening questions/directions to researchers are clear and relevant; ensure individuals involved in the screening/review process are appropriately qualified	HREA administrative processes reviewed and revised. HREA Board review staffing and qualifications	Completed Completed
Reduce or eliminate administrative tasks that do not appear to improve the ethics review process	As per above HREA administrative process review and revision	Completed
Develop criteria for changes to the ethics submission that require resolution prior to going to the HREB for review (i.e., missing documents) vs. changes that can be sent back in conjunction with HREB feedback	As per above HREA administrative process review and revision	Completed
Provide clear instructions on HREB submission requirements, deadlines and screening procedures	Develop guidance reference materials for researchers	Completed
Adopt the Canadian Association of Research Ethics Boards (CAREB) Guidance on Reporting of	Develop standard operating procedures in line with these guidelines	In progress

Unanticipated Problems Including Adverse Events to Research Ethics Boards in Canada		
Identify opportunities to improve or maximize functionality of the electronic HREB system	Work with MUN and stakeholders to ensure maximum utility	Ongoing
Improve templates and application forms	As per above HREA administrative process review and revision	Completed. Review and further revisions ongoing.
Establish criteria for deferring studies to future HREB meetings, and for requiring a full-board review of responses from researchers	Develop standard operating procedure	Deferral process not possible under HREA Act. Draft SOP developed, work ongoing.
Establish criteria for delegated review and implement delegated review procedures	Develop standard operating procedure	Draft SOP developed, work ongoing
Review the frequency of HREB meetings and potentially reduce if/when measures are implemented to improve meeting efficiency	Consider once other recommendations are implemented	TBD

Improve Outreach and Communication

Recommendations	Action	Status
HREB Improve outreach and connection with the research community	Expand membership Expand education sessions with researchers	Efforts to expand membership ongoing Expanded education sessions with researchers and will be ongoing
Identify available resources such as local experts or ad hoc reviewers with specific expertise to support the HREB reviews	Build on current processes	Ongoing

Develop educational resources to help research teams submit improved research applications	Develop further education materials for in person and self-directed learning	Completed
Review HREO/HREB email and letter templates to support improved communication	As per above HREA administrative process review and revision	Completed
Create relationships with other HREOs at other REBs to increase exposure to alternate review processes and HREO interactions with the HREB and Research teams	Expand formal and informal linkages	Ongoing

Governance, Roles and Reporting Responsibilities

Recommendations	Action	Anticipated Date of Completion
The HREA foster stronger relationships with the institutions and organizations relying on the HREB for review; establish mechanisms to seek regular input and receive/resolve complaints from the research community; collaborate with these institutions/organization to develop educational or other supports for research teams to improve the quality of ethics submissions	HREA Board establish formal communication mechanisms with institutions HREA Board establish policies re management of complaints	Ongoing Ongoing Draft policy developed, work ongoing
The HREA develop clear policy and procedures to support oversight of the HREB and REO with respect to effective and efficient operations, while ensuring the HREB is independent in its ethical decision making, including the following: • Develop clear policy and procedures outlining the roles and responsibilities and reporting requirements of the HREA, HREB, REB Chair(s) and REO personnel • Establish a formal process for reporting and managing	Develop policies in all area. Formalize performance management procedures Convene the Constituent Committee Establish review mechanisms for HREB members and recognition	Work ongoing Complete Recruitment for Constituent Committee ongoing Development of recognition and support strategies established and ongoing

concerns related to the performance of REO personnel, and for addressing REO personnel concerns regarding researcher conduct • Ensure the REO is dedicated to supporting the REB and the research community and that performance management processes apply to all members of the REO • Convene the constituent committee as described in the Act or a similar body with a strong understanding of research, research ethics, health care and patient/participant issues. • With the HREB, review the membership of the HREB to ensure it is representative of the research community • Develop measures to support and recognize the contribution of HREB Chairs and HREB members		