Summary of October 12, 2018 Report

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 REB review timelines, process and decision outcomes, REB workload and resources, and governance and accountability.

Key findings included the following:

Review Timelines

- HREB-CT review timelines have increased by 40% since 2016 despite a 22% decrease in the number of studies approved
- The average time to review outcome is longer for the HREB-CT (104 days) than the average time across multiple REBs in Ontario (62 business days)
- A direct comparison of REB review timelines across 6 studies approved by the HREB-CT as well as other REBs in Canada indicated the HREB-CT had the longest review time in 4 of the 6 studies
- Factors contributing to longer review times for the HREB-CT included Research Ethics Office (REO) screening processes and studies not be reviewed at the originally scheduled HREB-CT meeting

Review Processes

- Significant time and effort are spent on administrative considerations that often do not lead to substantive changes to the study overall
- Screening processes do not appear to provide measurable improvement to the quality of the review process and can lack understanding of study-specific context
- A proportionate approach to ethics review has not be adopted; delegated review processes are not used
- HREB-CT meetings are longer and more frequent than what would be expected considering the number of studies to be reviewed
- The REO/HREB-CT do not have updated SOPS and tools and templates could be improved
- Researchers are frustrated with the HREB-CT review process, timelines and their approach to research teams; researchers are concerned clinical trial opportunities are declining

Decision Outcomes

- An uncommonly high number of studies require re-review by the full board after the initial review

- A case study indicated a longer review period by the HREB-CT than other REBs, with policy considerations and communication challenges between the REO, HREB-CT and researcher contributing to the delay

REB Workload and Resources

- The REO has greater resource and more administrative support than comparator REBs; workload is impacted by processes related to screening and REB meetings.

Governance, Accountability and Roles

- The governance and accountability model for the HREA/HREA has the potential to support high quality and efficient ethical review, but lacks clarity and content with respect to policies and procedures to support the optimal functioning of model
- The reporting relationships between the HREA and the HREB, HREB Chairs and REO are not well defined
- The HREA's connection to the research community is limited; communication between researchers and the HREB-CT/REO is challenging and researchers lack an effective mechanism for addressing concerns
- The role of the HREA is not well understood by the HREB; there is a perceived lack of support for the HREB by the HREA

<u>Recommendations include the following:</u>

Review Processes

- Revise the REO 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
- Develop criteria for changes to the ethics submission that require resolution prior to going to the REB for review (i.e., missing documents) vs. changes that can be sent back in conjunction with HREB feedback
- Reduce or eliminate administrative tasks that do not appear to improve the ethics review process
- Provide clear instructions on REB submission requirements, deadlines and screening procedures.
- Adopt the Canadian Association of Research Ethics Boards (CAREB) Guidance on Reporting of Unanticipated Problems Including Adverse Events to Research Ethics Boards in Canada.
- Identify opportunities to improve or maximize functionality of the electronic REB system.
- Improve templates and application forms
- Establish criteria for deferring studies to future REB meetings, and for requiring a full-board review of responses from researchers
- Establish criteria for delegated review and implement delegated review procedures
- Review the frequency of REB meetings and potentially reduce if/when measures are implemented to improve meeting efficiency

Improve Outreach and Communication

- HREB Improve outreach and connection with the research community
- Identify available resources such as local experts or ad hoc reviewers with specific expertise to support the HREB reviews
- Develop educational resources to help research teams submit better research applications
- Review REO/HREB email and letter templates to support improved communication
- Create relationships with other REOs at other REBs to increase exposure to alternate review processes and REO interactions with the REB and Research teams

Governance, Roles and Reporting Responsibilities

- 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
- 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 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