

May-08-2020

Project Number: 8268

Project Title: Survey of Insurance Claims Process for Individuals with Communication Disorders After Traumatic Brain Injury

Principal Investigator: Dr. Lyn Turkstra

This will acknowledge receipt of your letters dated March 16, 2020 and April 24, 2020 which enclosed revised copies of the Information/Consent Form, Email Correspondences Survey, Protocol and the Application Form along with a response to the additional queries of the Board for the above-named study. These issues were raised by the Hamilton Integrated Research Ethics Board at their meeting held on February 18, 2020. Based on this additional information, we wish to advise your study had been given *final* approval from the full HiREB.

The following documents have been approved on both ethical and scientific grounds:

Document Name	Document Date	Document Version
Email-Correspondence-to-Organizations.2020.04.27 V3	Apr-27-2020	3
Email-Correspondence-to-Participants.2020.04.27 V3	Apr-27-2020	3
Final Survey 2020.03.15	Mar-15-2020	4
Protocol-Version 6-2020.04.27 (CLEAN)	Apr-27-2020	6
TBI Insurance Survey Consent 2020.03.15 CLEAN	Mar-15-2020	4

The following documents have been acknowledged:

Document Name	Document Date	Document Version
TCPS2_core_certificate	Apr-18-2017	1

In light of the current COVID-19 pandemic, while this study has been reviewed by HiREB and given final approval status, the actual conduct of the research needs to be performed in accordance with institutional restrictions with respect to Coronavirus (which means new subjects cannot be actively enrolled and most research staff will be limited with respect to access to other data sources for the time being).

Please Note: All consent forms and recruitment materials used in this study must be copies of the above referenced documents.

We are pleased to issue final approval for the above-named study for a period of 12 months from the date of the HiREB meeting on February 18, 2020. Continuation beyond that date will require further review and renewal of HiREB approval. Any changes or revisions to the original submission must be submitted on a HiREB amendment form for review and approval by the Hamilton Integrated Research Ethics Board.

PLEASE QUOTE THE ABOVE REFERENCED PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

Sincerely,



Dr. Mark Inman, MD, PhD
Chair, Hamilton Integrated Research Ethics Board

The Hamilton Integrated Research Ethics Board (HiREB) represents the institutions of Hamilton Health Sciences, St. Joseph's Healthcare Hamilton, Research St. Joseph's-Hamilton, and the Faculty of Health Sciences at McMaster University and operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada, and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations; For studies conducted at St. Joseph's Healthcare Hamilton, HiREB complies with the Health Ethics Guide of the Catholic Alliance of Canada