

Amendment Approval

Feb-14-2022

HiREB Project #: 13390

Project Submission Title: Repurposed Approved Therapies for Outpatient Treatment of Patients with Early-Onset COVID-19 and Mild Symptoms

Local Principal Investigator: Dr Edward Mills

Document(s) Approved:

Document Name	Document Date	Document Version
TOGETHER Summary of Protocol Changes 8Feb2022	Feb-08-2022	1
TOGETHER_MP_SAP_v3.0_8Feb2022_Clean	Feb-08-2022	3
TOGETHER_CRF_V7.0_8Feb2022_Clean	Feb-08-2022	7
TOGETHER_ICF_V4_8Feb2022_clean	Feb-08-2022	4
TOGETHER_MP_V4.0_8Feb2022	Feb-08-2022	4

This amendment has been reviewed and approved as submitted:

Full Research Ethics Board

Research Ethics Board Executive

Student Research Committee

Conditions:

In light of the current COVID-19 pandemic, while HiREB has reviewed and approved this application, the research must be conducted in accordance with institutional and/or public health requirements.

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, the Faculty of Health Sciences at McMaster University, and Niagara Health 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 Practice Guideline (ICH GCP); Part C Division 5 of the Food and Drug Regulations of Health Canada, Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations 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.