

Amendment Approval

Dec-20-2021

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
HiREB List of changes	Nov-24-2021	
TOGETHER_CRF_V6.0_18Nov2021_Clean	Nov-18-2021	6
TOGETHER_ICF_V3.1_18Nov2021_clean	Nov-18-2021	3.1
TOGETHER_MP_V3.1_16Nov2021	Nov-16-2021	3.1

Remove Study Coordinator: Alla Glushchenko Add Study Coordinator: Christina Guo

This amendment has been reviewed and approved as submitted:

[] Full Research Ethics Board

[X] 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.

Additional Chair Comments: HiREB does not see any ethical concerns with these changes. We remind the researchers that approval of this research covers only your role as the coordinating center, but does not cover the recruiting or consenting of participants or the conduction of the research at each of the participating centers.

Sincerely,

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Dr. Mark Inman, MD, PhD/Kristina Trim, PhD, RSW 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.