

Jun-25-2021

Project Number: 13390

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

Principal Investigator: Dr Edward Mills

This will acknowledge receipt of your letters dated May 4, 2021 and June 23, 2021 which enclosed revised copies of the Information/Consent Form, CRF, Questionnaires, 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 April 20, 2021. 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
Together_Protocol_V2.1_05May2021_Signed.docx	May-05-2021	Version 2.1
TOGETHER_CRF_V2.2_05May2021_Signed.docx	May-05-2021	Version 2.2
TOGETHER_SAP_V1.1_05May2021_Signed.docx	May-05-2021	Version 1.1
PROMIS Global Health Scale_23June2021	Jun-23-2021	NA
WHO Clinical Worsening Scale_23June2021	Jun-23-2021	NA
TOGETHER_ICF_V3.0_23June2021	Jun-23-2021	Version 3.0

The following documents have been acknowledged:

Document Name	Document Date	Document Version
Social and Behavioral Research Course Certificate_Edward Mills	Mar-29-2021	Version 1.0
Notes_Verified Translation Certificate	Mar-29-2021	NA
TOGETHER Trial_Budget	Jan-28-2021	Version 1.0
Brazil National Ethics Committee Approval 15Mar2021	Mar-15-2021	Version 1.0
Notes_StudyKey	May-02-2021	NA
Notes_Correspondence recruitment scripts_updated	May-04-2021	NA
Notes_Data Collection Form_updated	May-04-2021	NA
Health_Canada_Inquiry re COVID-19 clinical trial Mar2021	Feb-26-2021	Version 1.0

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 Corona virus (which may mean 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 April 20, 2021. 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