

Date: 11 October 2022

To: Dr. Andrew Pinto, Unity Health Toronto

CTO Project ID: 4133

Study Title: Canadian Adaptive Platform Trial of Treatments for COVID in Community Settings

Sponsor Study ID: N/A

Study Sponsor: Unity Health Toronto

Application Type: Clinical Trial Provincial Initial/CHEER Initial Application

Review Type: Full Board

Meeting Date: 10/Aug/2022

Date Approval Issued: 11/Oct/2022

Study Approval Expiry Date: 11/Oct/2023

Dear Provincial Applicant,

Thank you for submitting the above referenced study on behalf of all Ontario centres through the Clinical Trials Ontario Streamlined Research Ethics Review System. The Unity Health Toronto Research Ethics Board has reviewed the study and granted initial provincial approval as of the date noted above.

**Provincial documents approved:**

Document Name	Document Date
Appendix 4.1 - Initial contact script and Screening Form - Sept 9 2022	09/Sep/2022
Appendix 4.2- Pharmacist Script and Pharmacy Form - Sept 9 2022	09/Sep/2022
Appendix 4.3 - Recruitment poster - Sept 29 2022 Clean	29/Sep/2022
Appendix 4.4 - Letter to PBRN-associated providers - Sept 29 2022 Clean	29/Sep/2022
Appendix 4.5 - Letter to PBRN-associated patients from providers - Sept 29 2022	29/Sep/2022
Appendix 4.6 - Letter to providers after patient enrollment - Sept 29 2022	29/Sep/2022
Appendix 2.1 - ICF witness attestation form - Sept 29 2022	29/Sep/2022
Appendix 3.6 - Daily diary - Sept 29 2022 Clean	29/Sep/2022
CanTreatCOVID - Master Protocol - Sept 29 2022 Clean	29/Sep/2022
Appendix 2 - Information sheet and consent - Sept 9 2022 Clean	09/Sep/2022

**Provincial documents acknowledged:**

Document Name	Document Date
CanTreatCOVID - Budget & Budget Justification	17/May/2022
CanTreatCOVID - Appendix 5 - DSMC charter - July 27 2022	27/Jul/2022
CanTreatCOVID - Appendix 6.1 - ISA usual care - Aug 1 2022	01/Aug/2022
Appendix 1 - Master Linking Log and contact info - Sep 9 2022 Clean	09/Sep/2022
Appendix 8 - Adverse Event Log - Sept 9 2022	09/Sep/2022
Appendix 9 - Medication Log - Sept 9 2022	09/Sep/2022
CanTreatCOVID - Website PDF - Sept 29 2022	29/Sep/2022
Appendix 3.2 - Baseline data - Sept 29 2022 Clean	29/Sep/2022
Appendix 3.1 - Demographic data - Sept 29 2022 Clean	29/Sep/2022
Appendix 3.7 - Follow-up at day 1 - Sept 29 2022	29/Sep/2022

Appendix 3.3 - Follow-up at 28 days - Sept 29 2022 Clean	29/Sep/2022
Appendix 3.4 - Follow-up at 90 days - Sept 29 2022 Clean	29/Sep/2022
Appendix 3.5 - Follow-up at 36 weeks - Sept 29 2022 Clean	29/Sep/2022
Appendix 3.8 - End of treatment or study - Sept 29 2022	29/Sep/2022
Appendix 12 - Toll-free phone line contacts - Sep 29 2022	29/Sep/2022
PIA REB Request for Revisions Response Letter - Oct 6 2022	06/Oct/2022

**Note: Provincial REB approval does not confer ethics approval for participating centres. Each participating centre, including that of the Provincial Applicant, must submit the “Centre Initial Application” and receive approval from this REB prior to the conduct of the study at that centre. All other required institutional approvals must also be obtained prior to the conduct of the study.**

No deviations from, or changes to, the protocol should be initiated without prior written approval from Unity Health Toronto Research Ethics Board, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial (such as a change in telephone number).

REB members involved in the research project do not participate in the review, discussion or decision.

Unity Health Toronto Research Ethics Board operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; 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 (PHIPA 2004) and its applicable regulations. Unity Health Toronto Research Ethics Board is qualified through the CTO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP).

Please do not hesitate to contact us if you have any questions.

Sincerely,

David Mazer, MD  
Chair, Research Ethics Board

Michael Szego, PhD  
Vice Chair, Research Ethics Board

Zoe von Aesch, MD  
Vice Chair, Research Ethics Board

Melanie Tsang, MD  
Vice Chair, Research Ethics Board