**Date:** 15 November 2022

**To:** Jason McGuire, Research Ethics Board, Unity Health Toronto

**Re:** CTO Project ID: 4133

**Study Title:** Canadian Adaptive Platform Trial of Treatments for COVID in Community Settings (CanTreatCOVID)

**Sponsor Study ID:** N/A

**Study Sponsor:** Unity Health Toronto

**Application Type:** Provincial Amendment/CHEER Amendment

**Review Type:** Delegated

**Subject:** CanTreatCOVID – PIA REB Amendment 2 Request Letter

Dear Jason McGuire,

Please see below a description of the amendment requested for CanTreatCOVID.

Health Canada has provided a Notice of Authorization (NOA) for the Paxlovid x 5 Days treatment arm of the trial. Prior to providing the NOA, a few minor revisions were requested. To align version numbers of approved documents, updated documents are being submitted to Unity Health Toronto for approval and are outlined below.

Changes to Master Protocol & Associated Appendices

1. There is a typo in the CanTreatCOVID Amendment Tracker document header. The typo in was corrected. Additional columns were also added to the tracker for improved documentation of amendments.

The updated amendment tracker, titled, **Appendix 10 - Amendment tracker - Oct 28 2022** has been uploaded.

1. To better align with the ICH E2A definition of serious adverse events, the statement, “*We define SAE as an event that is fatal, life-threatening, results in disability that is persistent and significant, or results in a birth defect or congenital abnormality,*” has been revised to “*We define SAE as an event* ***or reaction to the study medication*** *that is fatal, life-threatening,* ***requires hospitalization****, results in disability that is persistent and significant, or results in a birth defect or congenital abnormality.*”

Although the ICH E2A definition includes, “…prolongation of existing hospitalization…,” we have excluded this in our protocol because patients currently hospitalized are not eligible for the trial, as per the exclusion criteria listed in Section 6.2 of the Master Protocol.

The updated Master Protocol, titled, **CanTreatCOVID - Master Protocol - Oct 28 2022**, has been uploaded.

Changes to Paxlovid x 5 Days Sub-Protocol

1. The Paxlovid x 5 Days sub-protocol incorrectly stated that Health Canada will be providing the PaxlovidTM medication. This statement has been revised to, “*Paxlovid™ will be provided by the Public Health Agency of Canada.*”

The updated Paxlovid x 5 Days sub-protocol, titled, **Paxlovid x 5 Days Sub-Protocol - Oct 28 2022**, has been uploaded.

Other

1. The Paxlovid x 5 Days NOA, titled, **Paxlovid x 5 days - Notice of Authorization - Nov 2 2022**, has been uploaded.

**Sincerely,**

**Andrew D. Pinto, MD CCFP FRCPC MSc**

**Principal Investigator**