

Date: 9 January 2024

To: Dr. Andrew Pinto, Unity Health Toronto

Participating Centres:

Contact Full Name	Contact Centre
Dr David Barber	Queen's University
Dr. Sakina Walji	Mount Sinai Hospital
Dr. Brianne Wood	Thunder Bay Regional Health Sciences Centre
Dr Anita Srivastava	St. Joseph's Health Centre Toronto
Dr. Ashley Verduyn	Providence Healthcare
Dr. Rachel Walsh	Sunnybrook Health Sciences Centre
Dr Dee Mangin	McMaster University
Dr. Andrew Pinto	St. Michael's Hospital
Dr Noah Crampton	University Health Network - Toronto Western Hospital
Dr. Aisha Lofters	Women's College Hospital
Dr. Brianna Orava	Royal Victoria Regional Health Centre
Dr Simone Dahrouge	Bruyère Research Institute

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: Provincial Amendment/CHEER Amendment

Amendment Reference/ID: Amendment 7

Review Type: Delegated

Date Approval Issued: 09/Jan/2024

Study Approval Expiry Date: 11/Oct/2024

Dear Provincial Applicant,

The Unity Health Toronto Research Ethics Board has reviewed the amendment to the study and granted approval as of the date noted above. This approval applies to all participating centres (listed above) that have received ethics approval to conduct the study.

**Provincial documents approved:**

Document Name	Document Date
Appendix 2 - Information sheet and consent - August 23, 2023_Clean-FR-Final	23/Aug/2023
Paxlovid x 5 Days_Appendix 1_Information sheet and consent_August 23, 20.FR-Final	23/Aug/2023
Appendix 2.1 - ICF witness attestation form - Sept 29 2022_fre-CA	29/Sep/2022
Appendix 3.7a - Daily diary - Oct 13 2022 Clean_fre-CA	13/Oct/2022
Appendix 3.7b - Daily diary (Flu Pro Plus) - Oct 13 2022_fre-CA	13/Oct/2022
Appendix 4.2- Pharmacist Script and Pharmacy Form - Sept 9 2022_fre-CA	09/Sep/2022

Document Name	Document Date
Appendix 4.5 - Letter to PBRN-associated patients from providers - Oct 13 2022 Clean_fre-CA	13/Oct/2022
Paxlovid x 5 days - Appendix 2 - Initial Contact Script and Screening Form - Oct 13 2022 Clean_fre-CA	13/Oct/2022
Paxlovid x 5 Days - Appendix 3 - Participant Information Sheet - Oct 13 2022_fre-CA	13/Oct/2022
Paxlovid x 5 Days - Appendix 4 - Wallet Contact Card - Oct 13 2022_fre-CA	13/Oct/2022
Appendix 4.1 - Initial-contact-script-and-Screening-Form-Sept-9-2022_FR_Clean	09/Sep/2022
Appendix 4.3 - Recruitment Poster - February 14 2023 - (8.5 x 11 in)_ FR	14/Feb/2023
Appendix 4.3a -Template for Social Media_FR	13/Jan/2023
Appendix 4.3b - Recruitment Poster 2 - February 9 2023 - (8.5 x 11 in)_ FR	09/Feb/2023
Appendix 4.3j - Recruitment video script - January 13 2023_FR	13/Jan/2023
Appendix 4.3k - Recruitment Poster 3 - February 14 2023 (8.5 x 11 in) _ FR	13/Jan/2023
Appendix 4.3L - Recruitment Poster 4 - May 26 2023 _ FR	26/May/2023
Appendix 4.3n - Study Sticker and Magnets - May 29 2023_FR	29/May/2023
Appendix 4.3o - Information Cards - May 29 2023_FR	29/May/2023
Appendix 4.3p - Posters with tear offs - May 29 2023_FR	29/May/2023
Appendix 4.4 - Letter to PBRN-associated providers - June 16, 2023_FR_Clean	16/Jun/2023
Appendix 4.6 - Letter-to-providers-after-patient-enrollment-Nov-3-2022-FR_Clean	03/Nov/2022
Paxlovid x 5 Days-Appendix-3.1_Standard-of-Care-Participant-Information-Sheet-June 16_FR	16/Jun/2023
UHT - Appendix 4.3a - Social Media Posts and Accounts - June 1 2023_FR	01/Jun/2023
UHT - Appendix 4.3g - Email to companies - March 14, 2023-FR	14/Mar/2023
UHT - Appendix 4.3h - Recruitment email - January 13 2023-FR	13/Jan/2023
UHT - Appendix 4.3i - Outreach from Workplace Health COVID-19 Team - January 13 2023-FR	13/Jan/2023
UHT Appendix 4.3u – Dicentra recruitment package.pdf	06/Dec/2023
UHT Appendix 4.3v – Radio ads script-dec 6 2023	06/Dec/2023
Apt-institute_french	16/Nov/2023
APT-institut-materials_french	16/Nov/2023
Boîte à outils de recrutement	16/Nov/2023
Contact_FR	16/Nov/2023
Job opportunities_french	16/Nov/2023
partners_FR	16/Nov/2023
Study-materials_FR	16/Nov/2023
Team_FR	16/Nov/2023
about_frenchreview	16/Nov/2023
Home_Frenchrevise	16/Nov/2023
News_french	16/Nov/2023
About	20/Oct/2023
Apt-institute	20/Oct/2023
Apt-institute-materials	20/Oct/2023
Contact	20/Nov/2023
Home	20/Oct/2023
Job-opportunities	20/Oct/2023
News-updates	20/Oct/2023
Partners	20/Oct/2023

Document Name	Document Date
Recruitment-toolkit	20/Oct/2023
Study-materials	20/Oct/2023
Team	20/Oct/2023

**Provincial documents acknowledged:**

Document Name	Document Date
Affidavit AA3217- September 19 2023	19/Sep/2023
Appendix 3.1 - Demographic data - Sept 29 2022 Clean_fre-CA	29/Sep/2022
Appendix 3.2 - Baseline data - Oct 13 2022 Clean_fre-CA	13/Oct/2022
Appendix 3.8 - Follow-up at day 1 - Oct 13 2022 Clean_fre-CA	13/Oct/2022
Appendix 3.9 - End of treatment or study - Oct 13 2022 Clean_fre-CA	13/Oct/2022
Paxlovid x 5 Days - Appendix 6 - Follow-up at Day 4 - Oct 13 2022_fre-CA	13/Oct/2022
Affidavit (French Translation)-November 24 2022	24/Nov/2022
Final REB Approval of the Project (2023-09-29) - MP-37-2023-9559	29/Sep/2023
Appendix 3.3 - Follow-up at 21 days - Dec 09 2022_CLEAN-fre-CA	09/Dec/2022
Appendix 3.4 - Follow-up at 28 days - Dec 09 2022_CLEAN-fre-CA	09/Dec/2022
Appendix 3.5 - Follow-up at 90 days - Dec 09 2022-CLEAN_fre-CA	09/Dec/2022
Appendix 3.6 - Follow-up at 36 weeks - Dec 09 2022-CLEAN_fre-CA	09/Dec/2022
Appendix 4.7 - Online self-screening form_EN and FR_05Jan2023	05/Jan/2023
Appendix-12_Toll-free-phone-line-contacts-Sep-29-2022_FR	29/Sep/2022
Celine Jean-Xavier attestation translation	07/Dec/2023
Pierre Cordeau attestation December 07 2023	07/Dec/2023

**ACTION(S) TO BE TAKEN FOR COMMUNICATION WITH PARTICIPANTS**

- 1. Communication with participants who are currently enrolled in the study and receiving study treatment or intervention: N/A**
- 2. Communication with participants who are currently being followed for the purposes of the study but are no longer receiving study treatment or intervention: N/A**
- 3. Communication with participants who are no longer being followed for the purposes of the study: N/A**

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