



## Research Ethics Board

700 University Avenue, 8<sup>th</sup> fl., Suite 8-600  
Toronto, Ontario, Canada, M5G 1Z5  
t: (416) 586-4875 f: (416) 586-4715  
www.mtsinai.on.ca

### Notification of REB Initial Approval (Full Board)

**Date:** May 25, 2020

**To:** Dr. Allison McGeer  
Department of Microbiology  
Division of Infection Control  
Mount Sinai Hospital  
600 University Avenue Room 171  
Toronto, Ontario

**Re:** 20-0095-A  
Control of COVID-19 outbreaks in long term care - Favipiravir (CONTROL-COVID - Favipiravir)  
(eSubmission)

**Sponsor:**

Appili Therapeutics

**REB Review Type:**

Full Board

**REB Meeting Date:**

13 May, 2020

**REB Initial Approval Date:**

25 May, 2020

**REB Expiry Date:**

25 May, 2021

**Documents Approved:**

Protocol (Dated: 13-May- 2020)

Consent Form: Residents (Dated: 20-May-2020)

Consent Form: Staff (Dated: 20-May-2020)

Staff Consent Script (Dated: 20-May-2020)

Resident/SDM Consent Script (Dated: 29-Apr-2020)

Adverse Events Form (Dated: 4/29/2020)

Case Report Form: for Residents (Dated: 29-Apr-2020)

Staff Daily Diary (Dated: 29-Apr-2020)

Case Report Form for: Staff (Dated: 08-May-2020)

14 Day Questionnaire for Staff (Dated: 17-May -2020)

Outbreak Line List (Received Date: 30-Apr-2020)

40 Day Questionnaire for Staff (Dated: 17-May -2020)

Introductory Letter - MD (Dated: 20-May-2020)

Recruitment Poster for Staff (Dated: 20-May-2020)

Recruitment Poster for LTCH Resident/SDM (Dated: 20-May-2020)

Introductory Letter for Facility Staff (Dated: 29-Apr-2020)

Introductory Letter for Facility Physicians (Dated: 29-Apr-2020)

Introductory Letter - Resident Council (LTCHs) (Dated: 20-May 2020)

Introductory Letter for Facility Administrator (Received Date: 30-Apr-2020)

Website Online Recruitment (LTCHs) (Received Date: 21-May-2020)

How Do I Collect My Own Nasal Swabs? (For Staff) (Received Date: 30-Apr-2020)

Favipiravir Information Sheet for Pharmacy (Dated: 29-Apr-2020)

Favipiravir Information Sheet Healthcare Providers (Dated: 20-May-2020)

Favipiravir Information Sheet for Residents/Substitute Decision Makers (Dated: 29-Apr-2020)

Information Sheet: Hydroxychloroquine Information for Healthcare Providers (Dated: 29-Apr-2020)

Information Sheet: Hydroxychloroquine Information for Non-Healthcare Professional Staff (Dated: 29-Apr-2020)

**Documents Acknowledged:**

Budget (Received Date: 30-Apr-2020)

Health Canada No Objection Letter (Dated: 18-May-2020)

Quick Fact Sheet Summary (Received Date: 30-Apr-2020)

Investigator's Brochure: for Favipiravir (Dated: 20-Mar-2020)

Product Monograph: for Hydroxychloroquine (Dated: 06-Jan-2020)

**Health Records Access:**

Yes

The above named study has been reviewed and approved by the Mount Sinai Hospital Research Ethics Board. If, during the course of the research, there are any serious adverse events, any confidentiality concerns, changes in the approved protocol or consent form, or any new information that must be considered with respect to the project, these should be



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brought to the immediate attention of the REB. In the event of a privacy breach, you are responsible for reporting the breach to the MSH REB and the MSH Corporate Privacy Office (in accordance with Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the MSH REB requires reports of inappropriate/unauthorized use of the information.

If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The REB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

The MSH Research Ethics Board operates in compliance with the Tri-Council Policy Statement 2, ICH/GCP Guidelines, Part C, Division 5 of the Food and Drug Regulations of Health Canada, Part 4 of the Natural Health Product Regulations, and the Medical Devices Regulations.

Sincerely,

A handwritten signature in dark ink, appearing to read "Shah", written over a light blue horizontal line.

Vibhuti Shah, MD, FRCPC, MSc  
Vice Chair, Mount Sinai Hospital Research Ethics Board