UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

Room 350-2
McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455

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https://research.umn.edu/units/irb

APPROVAL OF NEW STUDY

April 2, 2020

Radha Rajasingham

612-626-8171
radha@umn.edu

Dear Radha Rajasingham:

On 3/31/2020, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Pre-exposure Prophylaxis for SARS-Coronavirus-2: A Pragmatic Randomized Clinical Trial
Investigator:	Radha Rajasingham
IRB ID:	STUDY00009414
Sponsored Funding:	None
Grant ID/Con Number:	None
Internal UMN Funding:	None
Fund Management Outside University:	None
IND, IDE, or HDE:	IND #149252
Documents Reviewed with this Submission:	• CRFs, Category: Other; • FDA Correspondence, Category: Other; • FDA Label, Category: Drug Attachment; • Advertisement, Category: Recruitment Materials; • Patient information sheet, Category: Recruitment Materials; • Protocol tracked, Category: IRB Protocol; • Main informed consent, Category: Consent Form

The IRB determined that the criteria for approval have been met and that this study involves greater than minimal risk.

The IRB also made the following determinations for this study:

- This research has been approved to enroll pregnant women and the research holds out the prospect of direct benefit to the pregnant women. Consent from the mother is required.

The IRB approved the study from 4/2/2020 to 3/30/2021 inclusive. You will be sent a reminder from ETHOS to submit a Continuing Review submission for this study. You must submit your Continuing Review no later than 30 days prior to the last day of approval in order for your study to be reviewed and approved for another Continuing Review period. If Continuing Review approval is not granted before 3/30/2021, approval of this protocol expires immediately after that date.

You must also submit a Modification in ETHOS for review and approval prior to making any changes to this study.

If consent forms or recruitment materials were approved, those are located under the Final column in the Documents tab in the ETHOS study workspace.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the HRPP Toolkit Library on the IRB website.

For grant certification purposes, you will need the approval and last day of approval dates listed above and the Assurance of Compliance number which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003).

IMPORTANT: All human research conducted at the University of Minnesota must adhere to the IRB guidance and requirements, Office of the Vice President for Research guidance, and MHealth Fairview and Medical School guidance (if applicable) in response to the COVID-19 pandemic. While the IRB continues to review and approve research, this guidance takes precedence, meaning that some research activities, including enrollment of participants, may not take place at this time for certain types of research. All researchers should review the guidance often as it is updated frequently by the Human Research Protection Program.

Sincerely,

Clinton Dietrich, MA, CIP
Senior IRB Analyst

We strive to provide clear, consistent, and timely service to maintain a culture of respect, beneficence, and justice in research. Complete a brief survey about your experience.