[Hospital name] Joins National PCORnet® Study of Hydroxycloroquine to Prevent COVID-19 in Healthcare Workers

[Hospital name]'s workers invited to join heroesresearch.org study to fight COVID-19 together

DATELINE -- [Hospital name] today opened enrollment for a new clinical trial investigating whether an oral drug called hydroxychloroquine (brand name Plaquenil®) is better than placebo in preventing COVID-19 infection in healthy people working in healthcare settings. Known as the Healthcare Worker Exposure Response & Outcomes of Hydroxychloroquine (HERO-HCQ) Trial, the study is being conducted through clinical research sites in PCORnet, the National Patient-Centered Clinical Research Network. The trial will enroll 15,000 people from the HERO Registry, a community of thousands of people working in healthcare, that supports this and future trials, and will randomize participants to either one month of hydroxychloroquine or one month of placebo to examine whether the drug is effective in preventing COVID-19 infection.

"There is a lot of interest in testing this drug as a preventive agent for COVID-19 because it appeared to block SARS-CoV-2 from entering cells in lab studies," said Susanna Naggie, principal investigator for the HERO-HCQ Trial and Associate Professor at the Duke University School of Medicine. Hear more from Dr. Naggie in this video. "But like all medications, there are potential risks as well as benefits. Before we can make recommendations on using hydroxychloroquine to prevent COVID-19, we need solid evidence, and the HERO-HCQ trial will help provide this data to guide decision-making."

Researchers at [hospital name] plan to recruit at least 375 people into the study. All people working in healthcare settings who provide care, supplies, or services to patients at [hospital name] — such as nurses, therapists, physicians, emergency responders, food service workers, environmental services workers, interpreters, and transporters — are invited to first join the HERO Registry to determine their interest in the HERO-HCQ Trial. During the HERO Registry enrollment process, healthcare workers must answer "yes" to a question determining interest in being contacted about participation in a randomized clinical trial of hydroxychloroguine.

As a double-blind, randomized, placebo-controlled study, HERO-HCQ Trial participants will take either hydroxychloroquine or a placebo tablet for 30 days. Hydroxychloroquine is an oral prescription medication approved by the US Food & Drug Administration for the treatment of malaria and autoimmune diseases such as lupus and arthritis. Study participants will get nasal swab tests for COVID-19 and blood tests to detect the presence of antibodies at the beginning of the study and after four weeks. Researchers will also collect information about participants' health and ask them to fill out quality-of-life surveys. Different from typical studies that take months to collect and analyze data, researchers will analyze data from the study every two weeks.

"As soon as there is clear evidence of an effect, the lead investigators will stop the trial and make a recommendation," said [PI]. "If the evidence shows the drug provides no benefit in preventing COVID-19, that will still be a useful result — we will save time and resources and

look for other ways to help healthcare workers. If there is clear evidence of a benefit, we will recommend using the drug as preventative therapy."

Researchers at the <u>Duke Clinical Research Institute</u> designed and are coordinating the HERO-HCQ Trial. The <u>Patient-Centered Outcomes Research Institute</u> is providing up to \$50 million in funding. As partners of the [CRN], the PCORnet affiliate organization in [City], [hospital name], along with [other hospitals in the network] are conducting the trial. To learn more about the HERO research program or to join, visit https://heroesresearch.org. To understand current hydroxycloroquine evidence and why HERO-HCQ is important, read this <u>fact sheet.</u>

About [Hospital]