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Open Letter to the Investigators of the Oxford PRINCIPLE Trial on Ivermectin in COVID-19

The Front Line COVID-19 Critical Care Alliance wishes to raise concerns about the proposed design of the Oxford PRINCIPLE Trial of ivermectin in COVID-19. We believe that it is an ethical imperative to provide those considering participation a truthful account of the available evidence of ivermectin's efficacy in COVID-19. The existing evidence base demonstrating the efficacy for Ivermectin was recently presented to both the World Health Organization (WHO) and the National Institutes of Health.

Dr. Andrew Hill (WHO expert consultant) has posted a preliminary meta-analysis which includes 18 randomized controlled trials with over 2,100 patients included. This meta-analysis finds large, statistically significant reductions in time to clinical recovery, length of hospitalization, and death. These findings are further strengthened by "natural" controlled experiments that have occurred within numerous cities and regions of the world where mass ivermectin distribution or treatment, especially among older people, was closely followed by widespread and large reductions in both case counts and case fatality rates from COVID-19. Please note that our manuscript which reviewed both these epidemiologic data and the existing clinical trials evidence base concluded that ivermectin should be the standard of care in COVID-19. This manuscript has been accepted for publication in a prominent medical journal and can be found here: **↗ Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19.**

Inadequately communicating this information to potential participants would be a violation of the primary responsibilities of clinical researchers as directed by the Belmont report to protect human subjects of biomedical research. Nonmaleficence is a constant duty; that is, one ought never cause harm to a patient, particularly when patient care and medical research co-exist. It requires us to take steps to avoid harm or injury to the patient, either through acts of commission or omission. While we support your organization's impressive work, we must strongly question whether the use of placebo given current scientific knowledge about ivermectin meets the criteria for such an omission. The Declaration of Helsinki – Ethical Principles for Medical Research involving

Human Subjects" states that "when combining medical research with medical care, patients can only be studied... if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects."

In the next few weeks, the result of four more randomized studies involving more than 3,000 additional patients will provide an even greater understanding of the efficacy of Ivermectin in COVID-19. These studies' findings will be critical to guide your impressive organization in the ethical design of prospective trials comparing either the timing, dosage, or duration of treatment.

Sincerely,

The Front Line COVID-19 Critical Care Alliance

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Media: For more information, or to arrange for an interview, please contact press@flccc.net.

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*The FLCCC Alliance was organized in March, 2020 by a group of highly published, world renowned Critical Care physician/scholars – with the academic support of allied physicians from around the world – to research and develop lifesaving protocols for the prevention and treatment of COVID-19 in all stages of illness. Their **MATH+ Hospital Treatment Protocol** – introduced in March, 2020, has saved tens of thousands of patients who were critically ill with COVID-19. Now, the FLCCC's new **I-Mask+ Prophylaxis and Early At-Home Outpatient Treatment Protocol** with Ivermectin has been released – and is a potential solution to the global pandemic.*