

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Oushodh Vaban
Mohakhali,
Dhaka-1212, Bangladesh

Memorandum

Memo no: - DGDA/CTP-1/06/2016/ **121**

Dated: **19/08/2020**

To

Prof. Dr. Meerjady Sabrina Flora (MBBS, MPH, PhD)
Principal investigator & National Coordinator (WHO-Solidarity Trial)
Director
IEDCR & NIC
MoHFW, Mohakhali, Dhaka -1212, Bangladesh.

Subject: Approval of research protocol "An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care"

The research protocol of "An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care" is being approved under these conditions:

1. The research protocol is approved for the period of one year from the date of approval by DGDA.
2. The DGDA approval shall automatically be revoked after one year if the research is not started. After one year, you shall have to seek Approval for revalidation of the protocol by the RRC & ERC before starting the protocol.
3. The DGDA should be notified if the protocol is discontinued before the expected date of completion.
4. You should notify DGDA immediately of any serious or unexpected adverse effects on participants or unforeseen events that might affect continued acceptability of the protocol.
5. You shall obtain prior approval from DGDA for any modification in the approved research protocol and/or approved consent form(s), except in case of emergency to safeguard/eliminate apparent immediate hazards to study participants. Such changes must immediately be reported to DGDA.
6. You shall conduct the study in accordance with the DGDA approved protocol and shall fully comply with GCP guidelines.