



MEMORANDUM

Date: 3/1/2021

TO: Clifton Callaway, MD., Ph.D.
Principal Investigator for C3PO
Valerie L Durkalski-Mauldin, Ph.D.
Principal DCC Investigator for C3PO
To provide to Site IRBs

FROM: Nahed El Kassar, M.D., Ph.D.
Program Officer for C3PO

SUBJECT: Report of the 2/25/21 meeting of the NHLBI DSMB and final NHLBI determination for:

“Clinical Trial of COVID-19 Convalescent Plasma in Outpatients” (C3PO) Study

The purpose of this memorandum is to inform Study Investigators of the scope and outcome of the DSMB deliberations regarding the “C3PO” on 2/25/21. The National Heart, Lung, and Blood Institute (NHLBI) has reviewed the DSMB’s recommendations and the Institute’s determination is described at the end of this letter.

DSMB Description and Charge

This DSMB was appointed by the NHLBI and tasked with independent monitoring of data and overseeing participant’s safety for NHLBI-supported C3PO trial. The DSMB is responsible for safeguarding the interests of study participants, assessing the safety and efficacy of study procedures, and for monitoring the overall conduct of the trial. This independent Board includes senior experts in ethics, biostatistics, clinical trials, hematology, transfusion, pathology and viral immunology.

In preparation for the meeting, the following documents were circulated to the DSMB prior to the meeting: an open blinded report on 491 participants, a closed report with efficacy and futility interim analysis on 450 participants (50% of 900) with 15 days of follow-up who had completed their primary endpoint, a power point presentation for the open portion of the DSMB meeting with a study overview and addressing previous DSMB queries.

DSMB Recommendations

The DSMB recommends that:

- The *Clinical Trial of COVID-19 Convalescent Plasma in Outpatients (C3PO)* trial be stopped for futility;
- Enrollment into the C3PO trial be paused pending the Institute's review and consideration of the recommendation to stop the trial for futility; and
- Follow-up of recently enrolled participants continue to completion

The Institute accepted the DSMB recommendations

If you have any questions regarding this summary, please contact me at nahed.elkassar@mail.nih.gov or 301-827-8268.