



# National COVID-19 Convalescent Plasma Project

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August 24, 2020

## **Statement from CCPP19 leadership on recent FDA Emergency Use Authorization (EUA):**

We welcome the FDA's decision giving EUA status to convalescent plasma for COVID-19. The new EUA will relieve some of the burdens of administering this therapy, which will facilitate its optimal use and expand availability to more Americans.

While not a panacea, convalescent plasma addresses a gap in therapeutic options that looms especially large until widespread vaccination can be achieved. The available data reinforces the safety of convalescent plasma transfusion for COVID-19 and provides indications of a mortality benefit when infused within the first few days after diagnosis. This is consistent with its historical use and with a likely antiviral mechanism of action. At this time, a mortality benefit is not consistently discerned in advanced stages of COVID-19.

We appreciate the healthy debate over how to balance urgent need with our knowledge of efficacy in the middle of a new pandemic. In our estimation, the immediate clinical need, excellent safety profile of convalescent plasma, historical experience, animal data, and fundamental knowledge of humoral immunity led the FDA to make a reasonable decision in approving the EUA. Important questions remain about optimal use of convalescent plasma for COVID-19 and we support continued and ongoing clinical trials in this area. It is our hope that the lessons learned from COVID-19 will make humanity better prepared for when the next pandemic hits. The experience with plasma use against COVID-19 illustrates the need for having clinical trial protocols available off the shelf so that these can be deployed immediately rather than having to be developed and deployed during the epidemic crisis.

One major outcome of the EUA will be to make convalescent plasma easier to dispense for understaffed hospitals in underserved locations. Under the prior system, administrative and regulatory requirements took physicians away from patient care and introduced potential delays in plasma administration. Given the available evidence that plasma works best when given early, the new approval may remove barriers to optimal use.

We owe a debt of gratitude to the massive grassroots network of donors, organizers, medical professionals, hospitals, and blood banks whose combined efforts since last March have advanced this compelling option so far. We hope this recent development will further stimulate interest in donating plasma and blood for COVID-19.

Sincerely,

The COVID-19 Convalescent Plasma Program Leadership Group