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April 18, 2020

<First Name, Last Name>

<Title>, <Institute/Hospital Name>

<Address>

Dear Sir/Madam:

**RE: TREAMENT OF COVID–19 WITH CONVALESCENT PLASMA**

As you know Passive immunization for the prevention and treatment of human infectious diseases and its related concept of artificially acquired passive immunity can be traced back to the 20th century.

Convalescent blood products, obtained by collecting whole blood or plasma from a patient who has survived a previous infection and developed humoral immunity against the pathogen responsible for the infection in question, are a possible source of specific antibodies of human origin, which can be used to treat the infection in other compatible patients.

The recent Corona virus pandemic outbreak has turned the spotlight onto the use of convalescent plasma in the treatment of COVID-19 because it is a promising therapeutic strategy available in some cases, given the unavailability of vaccines, effective drugs or other specific treatments.

On April 13, 2020, the U.S. Food and Drug Administration published Recommendations for Investigational COVID-19 Convalescent Plasma at:

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

Primary access to such therapy is available through clinical trials, expanded access and Single Patient Emergency IND. The U.S. FDA has worked with multiple federal partners and academia to open an expanded access protocol to facilitate access to COVID-19 convalescent plasma across the nation. The Mayo Clinic currently has a National Expanded Access Treatment Protocol in place and an institute such as your hospital may access COVID-19 convalescent plasma for severely ill patients with COVID-19.

Detailed information on various aspect of expanded access is published at: <https://www.uscovidplasma.org/>

A 15-step workflow for obtaining Convalescent Plasma for the U.S. COVID-19 Expanded Access Program is published at: <https://www.uscovidplasma.org/#workflow>

AAPI is a 501 (c) 3 member association of physicians of Indian origin engaged in educational and charitable activities. Through its local chapters and local physician members, AAPI sincerely requests that your hospital prepare for and provide access to convalescent plasma for eligible COVID-19 patients by registering your institute/hospital as a site for the Convalescent Plasma for the U.S. COVID-19 Expanded Access Program.

Please find below the links to the protocol documents for the Expanded Access Program:

<https://www.uscovidplasma.org/#consent>

<https://www.uscovidplasma.org/pdf/COVID-19%20Plasma%20EAP.pdf>

Please find below the link for a hospital to register as a site for the Expanded Access Program: <https://redcap2.mayo.edu/redcap/surveys/?s=T9WEANE38T>

Please find below an email address for further inquiries on the Expanded Access Program: uscovidplasma@mayo.edu

Given the public health emergency that the COVID-19 pandemic presents, the U.S. FDA also is facilitating access to COVID-19 convalescent plasma through a Single Patient Emergency IND (eIND). Below is the link to download the Form FDA 3926 and an email address to submit it.

<https://www.fda.gov/media/98616/download>

CBER\_eIND\_Covid-19@FDA.HHS.gov

We thank you in advance for your willingness to prepare for helping the COVID-19 patient with a potentially lifesaving treatment.

Sincerely,

Local Member

Local Chapter

Regional Director

AAPI