MAYO CLINIC

Responsible Clinician Notification:

From: Mayo Clinic IRB

To: Michael Joyner

Cc: Amy Amsbaugh
Kylie Andersen
Brenda Anderson
Machiko Anderson
Sarah Baker
Philippe Bauer
Supriya Behl
Lori Bergstrom
Lisa Brumble
Katelyn Bruno
Zachary Buchholtz
Matthew Buras
Michelle Burtis
Brian Butterfield
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Andrew Clayburn
Kristin Cornwell
Joshua Dennis
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Adam Eggert
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Vitaly Herasevich
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David Hodge
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Claudia Libertin
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Jaime Long
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Andrew Miller
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Camille Van Buskirk
Matthew Vogt
Mark Wentworth

Emily Whelan
Chad Wiggins
Jeffrey Winters
Douglas Wood
Janelle Worthington
Abba Zubair

Re: **IRB Modification #:** Mod20-003312-33
Title: Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19
IRB#: 20-003312

Modification Approval Date: 6/11/2020

The above referenced modification is approved by expedited review procedures. The modification includes: 1) Addition of Note to File, dated June 9, 2020, describing external (Non-Mayo Clinic) collaborators from whom de-identified data (information) about patients hospitalized with COVID-19 will be received at Mayo Clinic; and 2) Appendix 1: Modification to the US Convalescent Plasma Program to create a control group for Efficacy Analysis.The modification constitutes a minor change to previously approved research, and therefore was eligible for expedited review in accordance with 45CFR46.110(b)(2) & 21CFR56.110(b)(2). The Reviewer determined the modification(s) pose no more than minimal risk to subjects.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and major protocol violations/deviations within 5 working days of becoming aware of the occurrence.
4) Compliance with applicable regulations for the protection of human subjects and with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer